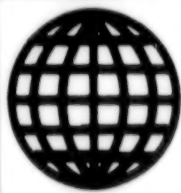


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25 January 1994



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# ***JPRS Report***

# **Science & Technology**

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***Central Eurasia  
Central Eurasian Health Laws***

# Science & Technology

## Central Eurasia

### Central Eurasian Health Laws

JPRS-UST-94-002

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## RF Law on Public Health

### Fundamentals of Russian Federation Legislation on Public Health Care

937C0386A Moscow ROSSIYSKAYA GAZETA  
in Russian 18 Aug 93 pp 4-7

[Law No 5487-1 on Fundamentals of Russian Federation Legislation on Public Health Care signed by RF President B. Yeltsin on 22 Jul 93]

[Text]Whereby it is governed by the Constitution of the Russian Federation, universally recognized principles, and standards of international law, and

whereby it recognizes the fundamental role of public health care as an inalienable condition of life of society and confirm the responsibility of the State for safeguarding and improving the health of citizens of the Russian Federation, and

whereby it aims to improve legal regulation and secure the priority of human and citizen rights and freedoms in the field of health care,

the Supreme Soviet of the Russian Federation hereby approves the Fundamentals of Legislation of the Russian Federation on Public Health.

#### Section I. General Statutes

##### Article 1. Public health care

Health care of citizens refers to the aggregate of political, economic, legal, social, cultural, scientific, medical, sanitary-hygienic and epidemic-control measures aimed at preservation and strengthening of the physical and mental health of everyone, maintaining a long active life, providing medical care in the event of illness.

The State guarantees health care for each individual in accordance with the Constitution of the Russian Federation and other legislative acts of the Russian Federation, Constitutions and other legislative acts of republics comprising the Russian Federation, universally recognized principles and standards of international rights, and international agreements of the Russian Federation.

##### Article 2. Basic principles of public health care

The basic principles for public health care are:—1) adherence to human and citizen rights in the field of health care and provision of State guarantees related to these rights;—2) priority of preventive measures in the field of health care;—3) availability of sociomedical care;—4) social protection of citizens in the event of illness;—5) responsibility of State executive and administrative agencies, enterprises, institutions and organizations, regardless of nature of ownership, and officials for ensuring the rights of citizens in the field of health care.

##### Article 3. Health care legislation of the Russian Federation

Legislation of the Russian Federation on public health care consists of relevant statutes in the Constitution of the Russian Federation and Constitution of republics comprising the Russian Federation, these Fundamentals and other legislative acts of the Russian Federation and republics of the Russian Federation passed in accordance with these fundamentals, as well as legal acts of autonomous oblasts, autonomous okrugs, oblasts, krays, the cities of Moscow and St. Petersburg.

These Fundamentals regulate the relations, in the field of public health care, of citizens, State executive and administrative agencies, business entities, individuals in State, municipal and private health care systems.

The legislative acts of republics of the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg should not limit the rights of citizens in the field of health care established by the present Fundamentals.

##### Article 4. Objectives of public health legislation of the Russian Federation

The object of legislation of the Russian Federation on public health care is to:—1) define the responsibility and competence of the Russian Federation, Russian Federation republics, autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg on questions of health care in accordance with the federal agreement, as well as to define the responsibility and competence of local self-government agencies in questions of public health care;—2) legally control activities in the field of public health of enterprises, institutions and organizations, regardless of nature of ownership, as well as State, municipal, and private health care systems;—3) define the rights of citizens and different population groups in matters of health care, and establish guarantees of their observance;—4) define the professional rights, duties and responsibility of medical and pharmaceutical workers, and establish guarantees of their social protection.

#### Section II. Competence in the Public Health Field of the Russian Federation, Republics of the Russian Federation, Autonomous Oblasts, Autonomous Okrugs, Krays, Oblasts, Cities of Moscow, St. Petersburg and Local Self-Government Agencies

##### Article 5. Competence of the Russian Federation

The following matters in the field of health care are within the purview of the Russian Federation, to: 1) pass and change federal laws on health care and check their implementation 2) protect human and citizen rights and freedoms in the field of health care 3) establish bases of federal State policy in the field of public health, develop and implement federal programs for development of health care, disease prevention, medical care, medical education for the public and other issues in the field of public health care 4) establish the structure of federal agencies that manage the State health care system, procedure for organizing them and activities 5) define the

share of health care expenses when setting up the republic budget of the Russian Federation, set up special funds for public health care, define taxation policy (including rebates on taxes, collections and other budgetary payments in the field of public health care 6) manage natural resources, protect the environment, provide for ecological safety 7) organize the State sanitation and epidemiological service of the Russian Federation, develop and pass federal sanitation rules and standards, and hygienic standards, provide for State sanitary and epidemiological oversight 8) organize a system for sanitary protection of the territory of the Russian Federation 9) implement measures directed toward saving human lives and safeguarding health in emergency situations, inform the public about circumstances in the zone of the emergency and steps taken 10) provide a unified technical policy in the pharmaceutical and medical industry, approve State standards of the Russian Federation, engineering conditions in plants producing items for medical purposes, and organize oversight so that they are met 11) certify (register, test and allow use of) drugs and disinfectants, immunobiological preparations and medical supplies, potent and toxic substances, narcotics, psychotropic agents, issue licenses for producing them, monitor their production, turnover and procedure for their use; certify products, work and services, issue permits for use of new medical technologies; 12) establish a unified federal system of statistical records and accounting in the field of health care;—14) develop common criteria and federal programs for training medical and pharmaceutical personnel, define the list of specialties in health care; establish basic preferential terms for medical and pharmaceutical personnel; 13) establish standards for quality of medical care and monitor adherence to them; develop and approve a basic program of mandatory health insurance for citizens of the Russian Federation; establish insurance premiums for mandatory health insurance for citizens of the Russian Federation; establish preferential treatment of different population groups with respect to sociomedical care and drugs 14) coordinate—in the field of public, family, mother, father, and child care—the work of State executive and administrative agencies, business entities, individuals in State, municipal and private health care systems; 15) establish procedure for expert medical evaluations; 16) establish procedure for licensing medical and pharmaceutical activities;—17) establish procedure to set up committees (commissions) dealing with ethics in the field of public health and their duties; 18) coordinate research, finance federal research programs dealing with public health care; 19) implement international collaboration of the Russian Federation and sign international agreements with the Russian Federation in the field of public health care.

Some of the authority in matters of public health care ascribed to the Russian Federation can be delegated to republics comprising the Russian Federation, autonomous oblasts, autonomous okrugs of the Russian Federation, krais, oblasts, cities of Moscow and St. Petersburg as established in the Federative agreement on differentiation of management

and authority of federal State agencies and agencies of sovereign republics of the Russian Federation, autonomous oblasts, autonomous okrugs of the Russian Federation, krais, oblasts, cities of Moscow and St. Petersburg in the Russian Federation.

#### **Article 6. Competence of republics of the Russian Federation**

The following matters in the field of health care are within the purview of republics of the Russian Federation, to:

- 1) pass legislative and other legal acts, monitor adherence to federal legislation, exercise legislative initiative in the field of public health care;
- 2) protect human and citizen rights and freedoms in the field of health care;
- 3) implement federal State policy in the field of public health care; define bases of State policy of republics of the Russian Federation in the field of public health care, execute federal programs for health care development; develop and execute republic-level programs to develop health care, disease prevention, medical care, medical education of the public and other matters in the field of public health care;
- 4) establish the structure of administrative agencies of the State health care system of republics of the Russian Federation, procedure for organizing them and their duties; develop a network of institutions in the State system of health care in republics of the Russian Federation; material and technical support of enterprises, institutions and organizations in the State health care system, monitor adherence to quality standards of medical care;
- 5) define the share of expenses for health care in setting up the republic-level budget of republics of the Russian Federation, set up special-purpose funds intended for public health care; approve programs of mandatory health insurance; establish additional preferential terms for some population groups with respect to sociomedical aid and drugs;
- 6) offer rebates on taxes, collections and other budgetary payments following established procedure for enterprises, institutions and organizations involved in public health care;
- 7) manage natural resources, protect the environment, provide for ecological safety;
- 8) protect the indigenous habitat and traditional lifestyle of small ethnic communities;
- 9) provide sanitary and epidemiological welfare and conditions for implementation of State sanitary and epidemiological oversight on the territory of Russian Federation republics; determine, for this purpose, the factors having an adverse effect on health of citizens, inform the public about them and implement measures to eliminate them, execute preventive, sanitary-hygienic, epidemic-control and environment-protective measures;
- 10) coordinate the work of State executive and administrative agencies, business entities, individuals in State, municipal and private health care systems in



the field of public health care; family, mother, father, and child care, sanitary and hygienic education of the public;

- 11) implement measures directed toward saving human lives and safeguarding health in emergency situations, inform the public about circumstances in the zone of the emergency and steps taken;
- 12) issue permits for use of new methods of prevention, diagnosis and treatment, new medical technologies in republics of the Russian Federation;
- 13) organize and coordinate training of health care personnel, establish preferential terms for such personnel in addition to those adopted on the federal level;
- 14) license medical and pharmaceutical work, monitor performance of municipal licensing commissions;
- 15) coordinate research, finance republic programs of research in the field of citizen health care;
- 16) inform the public regularly, including the use of mass media, about the incidence of socially significant diseases and diseases presenting a danger to others;
- 17) implement international collaboration in the field of public health care;
- 18) deal with other issues in the field of public health care that are not within the purview of the Russian Federation.

Administrative agencies of Russian Federation republics, by agreement with federal State agencies of the Russian Federation, can refer to the latter implementation of some of their powers in matters of public health care.

**Article 7.** Competence of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg

The following matters in the field of health care are within the purview of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg, to:

- 1) pass legal acts, monitor adherence to federal legislation, exercise legislative initiative in the field of public health care;
- 2) protect human and citizen rights and freedoms in the field of health care;
- 3) implement State policy of the Russian Federation in the field of public health care; execute federal programs to develop health care; develop and execute regional programs for development of health care, disease prevention, rendering medical care, medical education of the public and other issues in the field of public health care;
- 4) set up administrative agencies of the State health care system of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg; develop a network of institutions in State and municipal health care systems, as well as institutions of the system of social protection of the public; material and technical support of enterprises, institutions, and organizations in the State public health

system; check adherence to quality standards of medical care;

- 5) define the share of expenses for public health in setting up their own budget, set up special-purpose funds earmarked for public health; finance and implement development of primary medical and health care pertaining to other forms of medical care and drugs; implement measures for health insurance; establish additional preferential terms for some population groups in rendering sociomedical aid and supplying drugs;
- 6) provide rebates on taxes, collections and other budgetary payments following established procedure for enterprises, institutions and organizations involved in public health care;
- 7) coordinate the work in the field of public health of State executive and administrative agencies, executives, individuals in the State, municipal and private health care systems;
- 8) protect the indigenous habitat and traditional lifestyle of small ethnic communities;
- 9) manage natural resources, protect the environment, provide for ecological safety;
- 10) provide sanitary and epidemiological welfare and conditions for implementation of State sanitary and epidemiological oversight on subordinate territories; determine factors having an adverse effect on citizens' health, inform the public about them and carry out measures to eliminate them, implement preventive, sanitary-hygienic, epidemic-control and environment-protective measures;
- 11) protect families, mothers, fathers and children; educate the public in sanitation and hygiene;
- 12) execute measures to save human lives and protect them in emergency situations, inform the public about conditions in the zone of the emergency and steps taken;
- 13) license medical and pharmaceutical work, monitor performance of municipal licensing commissions;
- 14) organize and coordinate training of health care personnel;
- 15) inform the public regularly, including use of mass media, about the incidence of socially significant diseases and diseases presenting a danger to others;
- 16) implement international collaboration in the field of public health care;
- 17) deal with other issues in the field of public health care that are not within the purview of the Russian Federation. State agencies of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg, by agreement with federal State agencies of the Russian Federation, can refer to the latter implementation of some of their authority in matters of public health care.

**Article 8.** Competence of local self-government agencies

The following matters in the field of health care are within the purview of local self-government agencies, to:

- 1) check adherence to legislation in the field of public health care;

- 2) protect human and citizen rights and freedoms in the field of health care;
- 3) set up administrative agencies in the municipal health care system, develop a network of institutions in the municipal health care system, define the nature and scope of their work; create conditions for development of a private health care system; organize primary medical-sanitary and other types of socio-medical aid, make it accessible, check adherence to quality standards of medical care, provide citizens with drugs and medical supplies within the subordinate territory;
- 4) set up their own budget for health care expenses;
- 5) provide sanitary and epidemiological welfare of the public and conditions for implementation of State sanitary-epidemiological oversight within the subordinate territory; define factors having an adverse effect on health, inform the public about them, execute measures to eliminate them, implement preventive, sanitary-hygienic, epidemic-control and environment protecting measures;
- 6) coordinate and monitor performance of enterprises, institutions and organizations in the State and municipal health care systems within the limits of their authority, monitor quality of sociomedical aid in the private health care system;
- 7) create special-purpose funds for public health care; implement measures for mandatory health insurance of citizens;
- 8) license medical and pharmaceutical work within the subordinate territory at the request of the pertinent subject State administrative agency of the Russian Federation
- 9) protect the environment and provide ecological safety; eradicate consequences of disasters and natural calamities;
- 10) develop and provide for the work of institutions dealing with rehabilitation of the disabled and individuals with mental disorders, organize their training, professional retraining and job placement, develop specialized enterprises, shops and other forms of organization of industry for these population groups, as well as special institutions for patients with incurable diseases;
- 11) inform the public regularly, including use of mass media, about the incidence of socially significant diseases and diseases presenting a danger to others;
- 12) implement measures to protect families, mothers, fathers and children; sanitary and hygienic education of the public.

### **Section III. Organization of Public Health Care in the Russian Federation**

**Article 9.** Authority of highest Russian Federation State executive and administrative agencies in the field of public health care

The Supreme Soviet of the Russian Federation defines the main directions of federal State policy in the field of public health care, passes laws and approves federal programs on matters of public health care, approves the

Russian Federation republic budget, including the section on health care expenses, and monitors its implementation.

The president of the Russian Federation supervises implementation of the federal State policy in the field of public health care; at least once a year, he submits to the Supreme Soviet of the Russian Federation a report on State policy in the field of public health care and health status of the people in the Russian Federation.

The Russian Federation Government implements federal State policy in the field of public health care, develops, approves and finances federal programs for development of health care; coordinates in the field of public health care the work of State administrative agencies, as well as enterprises, institutions and organizations, regardless of nature of ownership, within limits stipulated in the legislation.

### **Article 10. Public health care funding**

The following are sources of financing public health care:—1) funds from budgets on all levels;—2) funds forwarded for mandatory and voluntary health insurance in accordance with the Law of the Russian Federation "On Health Insurance for Citizens in the Russian Federation";—3) funds from special-purpose funds earmarked for public health care;—4) funds from State and municipal enterprises, organizations and other business entities, social associations;—5) income from securities;—6) credit from banks and other creditors;—7) non-returnable and/or charitable contributions and donations;—8) other sources that are not prohibited by legislation of the Russian Federation.

### **Article 11. Sanitary-epidemiological welfare of the public**

Sanitary and epidemiological welfare is provided by implementation of hygienic and epidemic-control measures, adherence to sanitary rules and standards, and hygienic standards by State agencies, enterprises, institutions, organizations, public associations and citizens, by means of the system of State sanitary and epidemiological oversight, as well as a set of other organizational, legal and economic measures, in accordance with sanitary legislation of the Russian Federation.

### **Article 12. State health care system**

The State health care system refers to the Russian Federation Ministry of Health, health ministries of republics in the Russian Federation, health care administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, Russian Academy of Medical Sciences, Russian Federation State committee for sanitary and epidemiological oversight, which plan and implement steps to execute the Russian Federation State policy in the field of health care and for development of medical science, within the limits of their competence.

The State health care system also includes medical-preventive [therapeutic and preventive care] institutions, research institutions, educational institutions, pharmaceutical enterprises and organizations, pharmacies, preventive sanitary institutions, institutions of forensic medical expertise, services of material and technical support, enterprises that manufacture medical agents and equipment, and other enterprises, institutions and organizations, which are State property or subordinated to administrative agencies of the State health care system.

The State health care system includes medical-preventive institutions, pharmaceutical enterprises and organizations, and pharmacies, which are established, by ministries, departments, State enterprises, institutions of the Russian Federation apart from the Russian Federation Ministry of Health, and health ministries of republics in the Russian Federation. Regardless of subordination, enterprises, institutions and organizations in the State health care system are juridical entities and perform their duties in accordance with these Fundamentals, other legislative acts of the Russian Federation and republics in the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, as enforceable enactments of the Russian Federation Ministry of Health, health ministries of republics in the Russian Federation, health care administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

#### **Article 13. Municipal health care system**

Municipal health care systems comprise municipal health care administrative agencies and municipality-owned medical-preventive and research institutions, pharmaceutical enterprises and organizations, pharmacies, institutions of forensic medical expertise, educational institutions, which are juridical entities and perform their work in accordance with these Fundamentals, other legal acts of the Russian Federation, republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, enforceable enactments of the Russian Federation Ministry of Health, health ministries of republics of the Russian Federation, and local self-government agencies.

Municipal health care administrative agencies are responsible for sanitary and hygienic education of the public, providing a guaranteed volume of sociomedical aid accessible to the public, development of municipal health care system within the subordinate territory, monitor quality of sociomedical aid and supply of drugs by enterprises, institutions and organizations of the State and municipal private health care system, as well as individuals in private medical practice.

Enterprises, institutions and organizations of municipal health care systems are funded by budgets on all levels,

special-purpose funds earmarked for public health care, and other sources that are not prohibited by legislation of the Russian Federation.

#### **Article 14. Private health care system**

The private health care system includes medical-preventive and pharmaceutical institutions which are private property, as well as individuals engaged in private medical practice and private pharmaceutical business.

The private health care system includes medical-preventive, pharmacy, and research institutions, educational institutions created and financed by private enterprises, institutions and organizations, public associations, as well as persons.

The work of institutions in the private health care system is performed in accordance with these Fundamentals, other legal acts of the Russian Federation, republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, enforceable enactments of the Russian Federation Ministry of Health, health ministries of republics of the Russian Federation, and local self-government agencies.

#### **Article 15. Procedures and conditions of issuing licenses to enterprises, institutions and organizations in State, municipal, and private health care systems**

Enterprises, institutions and organizations in State, municipal and private health care systems can carry on their work only if they are licensed for their chosen type of work.

Enterprises, institutions and organizations in State, municipal and private health care systems are licensed on the basis of a certificate indicating that the conditions under which they operate conform to established standards. In cases where several medical specialties are involved, each specialty is listed separately on the license.

These licenses and certificates are issued by licensing commissions set up by the subject State administrative agency of the Russian Federation, or local administration at the request of the pertinent subject State administrative agency of the Russian Federation. The licensing commissions consist of representatives of the subject State administrative agency of the Russian Federation, or local administration, health care administrative agencies, professional medical and pharmaceutical associations. Licensing commissions are responsible for the validity of their decisions.

If the operating conditions at enterprises, institutions and organizations in State, municipal or private health care systems do not conform to the established standards, a license and certificate are not issued. Also, the licensing commissions can define the allowable types of work or they can schedule relicensing.



Unscheduled licensing is allowed at the initiative of health care administrative agencies, medical-preventive institutions, pharmacies, pharmaceutical enterprises and organizations, professional medical and pharmaceutical associations.

Licenses can be revoked or suspended by licensing commissions if enterprises, institutions and organizations fail to meet requirements and quality standards of medical care. A complaint against the decision of a licensing commission may be filed in court by officials of enterprises, institutions and organizations.

The procedure and conditions of issuing licenses to enterprises, institutions and organizations of State, municipal and private health care systems are established by the Russian Federation Government.

**Article 16.** Committees (commissions) for ethics in the field of public health care

Public health ethics committees (commissions) may be set up under State executive and administrative agencies, enterprises, institutions, organizations in the State or municipal health care system to protect the rights of the individual and those of different population groups in this field, to participate in elaboration of medical ethics standards and resolve problems related to infractions thereof, in preparation of recommendations on priority directions of clinical and research work, to solve other problems in the field of public health care.

Ethics committees (commissions) for health care matters consist of individuals representing the interests of the community, including specialists in medical ethics, jurists, scientists and artists, representatives of the clergy, professional medical associations, professional unions and other public associations.

The statute on procedure for setting up and running health care ethics committees (commissions) is approved by the Supreme Soviet of the Russian Federation.

#### **Section IV. Citizen Rights in the Field of Health Care**

**Article 17.** Rights of Russian Federation citizens to health care

Citizens of the Russian Federation have the inalienable right to health care. This right is provided by protecting the environment, providing beneficial working, living, recreational, rearing and educational conditions for citizens, by means of producing and marketing quality foodstuffs, as well as offering accessible sociomedical aid to the public.

The State provides health care for citizens, regardless of sex, race, nationality, language, social status, occupation, place of residence, attitude toward religion, convictions, membership in public associations, as well as other circumstances.

The State guarantees protection of citizens against all forms of discrimination because of any illness. Persons guilty of such discrimination are liable under the established law.

Citizens of the Russian Federation who are abroad, are guaranteed the right to health care in accordance with international agreements of the Russian Federation.

**Article 18.** Right of foreign citizens, stateless individuals and refugees to health care

Foreign citizens residing on Russian Federation soil are guaranteed the right to health care in accordance with international agreements of the Russian Federation.

Stateless individuals who are permanent residents of the Russian Federation and refugees enjoy the right to health care equal to that of citizens of the Russian Federation, unless otherwise stipulated in international agreements of the Russian Federation.

The procedure for rendering medical care to foreign citizens, stateless individuals and refugees is defined by the Russian Federation Ministry of Health and health ministries of republics of the Russian Federation.

**Article 19.** Citizen right to information about factors affecting health

Citizens have the right to receive reliable and timely information regularly about factors that help safeguard health or have a deleterious effect, including information about sanitary-epidemiological welfare in the region of their residence, sensible diet, industry, work, services and their conformity to sanitary standards and rules, other factors. This information is provided by local administration through the mass media or directly to citizens upon request following procedure established by the Russian Federation Government.

In the interests of citizen health care, mass media advertisement for alcoholic beverages and tobacco products is prohibited. Infraction of this standard is subject to liability as established by legislation of the Russian Federation.

**Article 20.** Citizen right to sociomedical aid

In case of illness, inability to work and other instances, citizens have the right to sociomedical aid, which includes preventive, therapeutic, diagnostic, rehabilitation, orthopedic prosthetic and dental prosthetic care, as well as social services pertaining to care of the sick, incapacitated and disabled, including payment of temporary disability benefits.

Socio-medical aid is rendered by medical, social workers and other specialists in institutions of State, municipal and private health care systems, as well institutions in the system of social protection of the public.

Citizens have the right to free medical care in State and municipal health care systems, in accordance with legislation of the Russian Federation, republics of the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

The guaranteed volume of free medical care is provided to citizens in accordance with programs of mandatory health insurance.

Citizens have the right to additional medical and other services on the basis of programs of voluntary health insurance, as well as resources of enterprises, institutions and organizations, their personal resources and other sources that are not prohibited by legislation of the Russian Federation.

Citizens have the right to preferential terms for prostheses, orthopedic, corrective items, hearing aids, transportation and other special items. The categories of citizens who have this right, as well as conditions and procedure for obtaining preferential orthopedic- and dental-prosthetic aid are determined by the Russian Federation Government.

Citizens have the right to obtain expert medical opinions, including independent ones that are provided at their personal request in specialized institutions in accordance with Article 53 of these Fundamentals.

Children, adolescents, students, invalids and pensioners engaged in exercise have the right to free medical supervision.

Employed citizens have the right to benefits if they are quarantined, when they are sent home from their work by the sanitary and epidemiological service due to communicable illness of others. If minors or citizens deemed incompetent according to procedure established by law are quarantined, benefits are issued to one of the parents (or other legal representative) or other family member, as established by legislation of the Russian Federation.

In case of illness, employed citizens have the right to three days of unpaid leave per year, which is granted at the personal request of a citizen without submitting a medical document to certify presence of illness.

#### **Article 21. Health care for citizens engaged in different occupations**

Employees in occupations, industries, enterprises, institutions and organizations, the list of which is approved by the Russian Federation Government, undergo mandatory examination when hired and periodic physical examinations for the purpose of protecting health, preventing communicable and occupational diseases.

A citizen may be deemed temporarily (for a term of no more than five years and with the right of subsequent recertification) or permanently unfit for reasons of health to perform some types of professional work and work related to a source of increased hazard. Such a

decision is made on the basis of expert socio-medical opinion in accordance with the list of medical contraindications, and it may be appealed in court.

The list of medical contra-indications for some types of professional work and work related to a source of increased hazard is established by the Russian Federation Ministry of Health and revised at least once every five years.

Employers are responsible for allocating funds for mandatory and periodic physical examinations for blue- and white-collar workers in cases and order stipulated by legislation of the Russian Federation and republics of the Russian Federation.

#### **Section V. Rights of Different Population Groups in the Field of Health Care**

##### **Article 22. Family rights**

The State assumes the responsibility of family health care.

Each citizen has the right, when medically indicated, to free consultations on family planning matters, socially significant diseases and diseases presenting a hazard to others, medical and psychological aspects of family and marital relations, as well as medical genetic, other consultations and examinations in institutions of the State or municipal health care system for the purpose of preventing possible hereditary diseases in offspring.

By agreement of all adult family members living together, the family has the right to choose a family physician who provides it with medical care determined by its residence.

Families with children (first of all, incomplete ones rearing incapacitated children and children left without parental care) have the right to preferential treatment in the field of public health care as established by legislation of the Russian Federation, republics of the Russian Federation, and legal acts of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

In the interests of a child's treatment, at the parents' discretion, one of the parents or another family member is granted the right to remain in a hospital with the child throughout his hospitalization, regardless of the child's age. A medical certificate [excuse from work] is issued by the State or municipal health care system to an individual who stays with a hospitalized child.

Benefits are paid in the case of quarantine to care for a sick child up to seven years old to one of the parents (or other legal representative) or other family member for the entire duration of quarantine, out-patient treatment or hospital stay with the child, whereas benefits to care for a sick child over the age of seven years are paid for a period not exceeding 15 days if a longer term is not required for medical reasons.



**Article 23. Rights of pregnant women and mothers**

The State gives the right to work to pregnant women under conditions conforming to their physiological distinctions and health.

Each woman is provided with specialized medical care during pregnancy, during and after parturition at an institute of the State or municipal health care system at the expense of special-purpose funds earmarked for public health care, as well as other sources that are not prohibited by legislation of the Russian Federation.

During pregnancy and in connection with the birth of a child, as well as during care of sick children up to 15 years old, women have the right to benefits and paid leave following procedure established by law.

The guaranteed term of paid maternity leave is determined by legislation of the Russian Federation. The leave may be extended in accordance with legislative acts of republics of the Russian Federation, and legal acts of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

The State guarantees appropriate nutrition, including cases where there is a need for supplying food through special food centers and stores to pregnant women, nursing mothers, as well as infants up to three years old, when ordered by physicians in accordance with procedure established by the Russian Federation Government, and governments of republics of the Russian Federation.

**Article 24. Rights of minors**

In the interests of safeguarding health, minors have the right to: 1) clinical observation and treatment by child and adolescent services following the procedure established by the Russian Federation Ministry of Health, and health ministries of republics of the Russian Federation; 2) sociomedical aid and nutrition on preferential terms established by the Russian Federation Government funded by budgets on all levels; 3) sanitary-hygienic education, schooling and work under conditions conforming to their physiological distinctions and health, and precluding their exposure to deleterious factors; 4) free medical consultations funded by budgets on all levels for determination of fitness for work; 5) receive necessary information about their health in terms they can understand.

Minors over 15 years old have the right to give their voluntary informed consent to medical interventions or to refuse them in accordance with articles 32, 33 and 34 of these Fundamentals.

At the request of parents or their substitutes, minors with physical or mental defects may be confined in institutions of the social protection system funded by budgets on all levels, charitable and other foundations, as well as resources of the parents or their substitutes.

**Article 25. Rights of military personnel, citizens subject to the draft and enlistees**

Military personnel have the right to medical certification of fitness for military service and early dismissal from military service on the basis of conclusions of a military medical commission.

Citizens subject to the draft and enlistees [refers to those who join up voluntarily] undergo medical certification and have the right to obtain full information about medical contraindications to military service and indications for deferral or excuse from the draft for military service for health reasons.

In the event of disagreement with the conclusion of a military medical commission, military personnel, citizens subject to the draft and enlistees have the right to obtain an independent expert medical opinion in accordance with Article 53 of these Fundamentals and/or appeal the conclusions of the military medical commissions in legal form.

Military personnel, citizens subject to the draft and enlistees have the right to medical care in institutions of the State or municipal health care systems.

The procedure for organizing medical care of military personnel is established by legislation of the Russian Federation, enforceable enactments of the Russian Federation Ministry of Defense and other ministries, State committees and departments in which military service is stipulated by law. The work of medical commissions of military commissariats is implemented and funded by the Russian Federation Ministry of Defense and other ministries, State commissions and departments, in which military service is stipulated by law.

**Article 26. Rights of the elderly**

Elderly citizens (who have reached the age established by legislation of the Russian Federation for receipt of an old-age pension) have the right to sociomedical aid at home, in institutions of the State or municipal health care system, as well as institutions of the system of social protection of the public, and to receive drugs, including some on preferential terms. Socio-medical aid to the elderly, including single elderly people and members of families consisting only of pensioners, is directed toward treating existing diseases and providing care, maintenance of active life and social protection in the event of illness and inability to take care of their essential needs.

Elderly citizens have the right, on the basis of a medical conclusion, to sanatorium, resort and rehabilitation therapy free of charge or on preferential terms at the expense of funds in social insurance, social protection agencies, and by enterprises, institutions and organizations with their consent.

**Article 27. Rights of invalids**

Invalids, including children and those who are disabled since childhood, have the right to socio-medical aid,

rehabilitation, supply of drugs, prosthesis, orthopedic prosthetic items, transportation on preferential terms, as well as vocational training and retraining.

Invalids who are unfit for work have the right to free sociomedical aid in institutions of the State or municipal health care system, care in the home and, if they are unable to take care of their essential needs, to care in institutions of the system of social protection of the public.

The procedure for rendering sociomedical aid to the disabled and list of preferential benefits for them are determined by legislation of the Russian Federation and republics of the Russian Federation. Agencies of the State, autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg can establish additional benefits for the disabled within the limits of their competence.

One of the employed parents or individuals replacing them are granted four additional paid days of leave per month, which can be used by one of the above-mentioned individuals or shared among them at their discretion, in order to care for disabled children or those disabled since childhood up to the age of 18 years.

**Article 28. Rights of citizens in emergency situations and regions with ecological problems**

Citizens who have suffered because an emergency situation have the right to free medical care, sanatorium, resort and rehabilitation therapy, hygienic and epidemic-control measures to overcome the consequences of the emergency situation and lower the risk to their life and health.

Citizens of the Russian Federation residing in regions, which are declared in accordance with legislated procedure to have ecological problems, are guaranteed free medical care, medical-genetic and other consultations and examinations when they get married, as well as sanatorium, resort and rehabilitation therapy, drugs, immunobiological agents and medical items on preferential terms.

Citizens who have been injured when saving people and rendering medical care in emergency situations are guaranteed free treatment, including sanatorium-resort therapy and all forms of rehabilitation, as well as financial compensation following procedure established by legislation of the Russian Federation.

**Article 29. Rights to medical care of individuals who have been detained, taken into custody, incarcerated, or under administrative arrest**

Individuals who are detained, taken into custody, incarcerated, or under administrative arrest have the right to medical care including, if necessary, care in institutions of the State or municipal health care system, which is funded by budgets on all levels.

Pregnant women, women in labor and in the postpartum period have the right to specialized care, including care given in maternity homes. Creches with qualified personnel are set up in incarceration facilities provided for mothers with infants up to the age of one year. It is prohibited to test new diagnostic, preventive and therapeutic methods, as well as drugs, carry out biomedical experiments on individuals who are detained, taken into custody, incarcerated, or under administrative arrest.

With respect to incarcerated individuals, the contract for voluntary health insurance is not in effect for the duration of their sentences.

The procedure for organizing medical care of individuals who are detained, taken into custody, incarcerated, or under administrative arrest is established by legislation of the Russian Federation, and enforceable enactments of the Ministry of Internal Affairs of the Russian Federation and Health Ministry of the Russian Federation.

#### **Section VI. Rights of Citizens When Receiving Sociomedical Aid**

##### **Article 30. Patient rights**

When seeking medical care and receiving it, the patient has to right to:

- 1) respectful and human attitude on the part of medical and service personnel;
- 2) choice of a physician, including family and attending physician, with consideration of his agreement, as well as choice of preventive medical institution in accordance with the contracts for mandatory and voluntary health insurance;
- 3) examination, treatment and upkeep under conditions conforming to sanitary and hygienic requirements;
- 4) have a conference of physicians and consultations with other specialists at his request;
- 5) relief from pain related to illness and/or medical intervention by available methods and agents;
- 6) have information about his seeking medical care, health status, diagnosis and other information obtained in the examination and treatment kept confidential, in accordance with Article 61 of these Fundamentals;
- 7) give his voluntary informed consent to medical intervention in accordance with Article 32 of these Fundamentals;
- 8) refuse medical intervention in accordance with Article 33 of these Fundamentals;
- 9) receive information about his rights and duties, and his condition in accordance with Article 31 of these fundamentals, as well as to choose individuals to whom information about his condition can be given in the interests of the patient;
- 10) receive medical and other services within the limits of programs of voluntary health insurance;
- 11) payment of damages in accordance with Article 68 of these Fundamentals in case his health was harmed when medical care was received;

- 12) access to a lawyer or other legal representative to protect his rights;
- 13) access to clergy or, when hospitalized, conditions to serve religious rites, including a separate room if this does not disrupt the internal schedule of the hospital.

If a patient's rights are violated, he can complain directly to the administrator or other official of the medical-preventive institution in which he receives medical care, pertinent professional medical associations and licensing commissions, or in court.

#### **Article 31. Citizen's right to information about his health**

Every citizen has the right to receive available information, in terms he can understand, about his health, including information about test results, existence of disease, diagnosis and prognosis, methods of treatment, risks involved in the latter, possible variants of medical interventions, their consequences and results of treatment received.

Information about his health is given to the citizen or, in the case of individuals under the age of 15 and those deemed incompetent according to procedure established by law, to their legal representatives by the attending physician, department chief of a medical-preventive institution or other specialists directly involved in examination and treatment.

Information about health cannot be given to a citizen against his will. In cases of a poor prognosis on development of a disease, the information should be reported in a tactful way to the citizen and his family, provided the citizen has not prohibited giving it to them and/or has not appointed someone to whom such information should be given.

The citizen has the right to view medical documentation reflecting his health status and to have consultations about it with other specialists. At the citizen's request, he is furnished copies of medical records reflecting the condition of his health, provided they do not touch upon the interests of a third party.

The information contained in medical records of a citizen is privileged and can only be furnished without the citizen's permission under conditions stipulated in Article 61 of these Fundamentals.

#### **Article 32. Consent to medical intervention**

Voluntary informed consent of the citizen is a mandatory prerequisite of medical intervention.

In cases where the citizen's condition does not permit him to express his wishes and the medical intervention is urgent, the question of performing it in the interests of the citizen is decided by a conference of physicians and, if it is impossible to hold such a conference, by the attending (on-duty) physician who subsequently informs officials of the medical-preventive institution.

Consent for medical intervention on individuals under the age of 15 years and citizens deemed incompetent according to procedure established by law is given by their legal representatives after reporting to them the information stipulated in the first part of Article 31 of these Fundamentals. In the absence of legal representatives, the decision on medical intervention is made by a conference of physicians and if it is impossible to hold such a conference, by the attending (on-duty) physician who subsequently informs officials of the medical-preventive institution and legal representatives. Refusal of medical intervention

A citizen or his legal representative has the right to refuse medical intervention or demand that it be stopped, with the exception of situations stipulated in Article 34 of these Fundamentals.

If medical intervention is refused, an explanation of possible consequences must be offered, in terms the citizen or his legal representative can comprehend. The refusal of medical intervention and indication of possible consequences are recorded in the medical record and signed by the citizen or his legal representative, as well as the health care worker.

If parents or other legal representatives of individuals under the age of 15 years, deemed incompetent according to procedure established by law, refuse medical care necessary to save the life of said individuals, the hospital has the right to appeal to court to protect the interests of said individuals.

#### **Article 34. Medical aid without consent of citizens**

Medical aid (medical certification, hospitalization, observation and isolation) without the consent of citizens or their legal representatives is permitted for individuals with diseases that present a hazard to others, suffering from serious mental illness or individuals who have committed socially dangerous acts, on the basis and following procedure established by legislation of the Russian Federation.

The decision to carry out medical certification and observation of citizens without their consent or the consent of their legal representatives is made by a physician (conference of physicians), while the decision for hospitalization of citizens without their consent or the consent of their legal representations is made by a court.

Rendering medical aid without consent of citizens or consent of their legal representatives involves epidemic-control measures and is regulated by sanitary legislation.

Certification and hospitalization of individuals with serious mental illness is performed without their consent following procedure established by the Law of the Russian Federation "On Psychiatric Care and Guarantees of Citizen Rights When Rendered."

As to individuals who have committed socially dangerous acts, compulsory medical steps can be taken on

the basis and following procedure established by legislation of the Russian Federation.

#### **Section VII. Medical services in family planning and birth control**

##### **Article 35. Artificial insemination and embryo implants**

Every adult woman of child-bearing age has the right to artificial insemination and embryo implantation.

Artificial insemination of a woman and implantation of an embryo are performed in institutions licensed for this type of activity, with the written permission of the spouse (or a single woman).

Information about performed artificial insemination and embryo implantation, as well as identity of the donor, is privileged.

A woman has the right to information about the procedure for artificial insemination and embryo implantation, about medical and legal aspects of consequences, about results of medicogenetic testing, external data and nationality of the donor, which is furnished by the physician who performs the medical intervention.

Illegal performance of artificial insemination and embryo implantation are subject to criminal liability as established by legislation of the Russian Federation.

##### **Article 36. Artificial abortion**

Every woman has the right to decide independently the question of motherhood. Artificial abortions are performed at a woman's request within the first 12 weeks of the gestation period, when socially indicated within 22 weeks, and any stage of pregnancy whenever medically indicated and with the woman's consent.

Artificial abortions are performed within the limits of programs of mandatory health insurance in institutions licensed for this type of activity by physicians with special training.

The list of medical indications for artificial abortion is determined by the Russian Federation Ministry of Health and the list of social indications, according to the statute approved by the Russian Federation Government.

Illegal abortions are subject to criminal liability as established by legislation of the Russian Federation.

##### **Article 37. Medical sterilization**

Medical sterilization, as a special intervention to deprive an individual of reproductive capacity or as a method of contraception, can be performed only upon written request of a citizen at least 35 years old or having at least two children, and regardless of age and number of children when medically indicated and with the consent of the citizen.

The list of medical indications for sterilization is defined by the Russian Federation Ministry of Health.

Medical sterilization is performed in institutions of the State or municipal health care system, which are licensed for this form of activity.

Illegal medical sterilization is subject to criminal liability as established by legislation of the Russian Federation.

#### **Section VIII. Guarantees of Sociomedical Aid to Citizens**

##### **Article 38. Primary medico-sanitary aid**

Primary medicosanitary aid is a form of medical service that is basic, available and free to each citizen, and it comprises treatment of the most common diseases, as well as trauma, poisoning and other emergency conditions; implementation of sanitary-hygienic and epidemic-control measures, medical prevention of the most important diseases; sanitary-hygienic education; implementation of steps to protect families, mothers, fathers and children, other measures related to rendering medico-sanitary aid to citizens in the area of their residence.

Primary medico-sanitary aid is provided by institutions in the municipal health care system and sanitary-epidemiological service. Institutions of the State and private health care systems may also render primary medico-sanitary aid on the basis of contracts with health insurance organizations.

The scope of primary medico-sanitary aid is determined by the local administration, in accordance with territorial programs of mandatory health insurance.

The procedure for rendering primary medicosanitary aid is established by administrative agencies of municipal health care systems on the basis of enforceable enactments of the Russian Federation Ministry of Health, State Committee for Sanitary and Epidemiological Oversight of the Russian Federation, health ministries of republics of the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

Primary medico-sanitary aid is funded by the municipal budget, special-purpose funds earmarked for public health care, and other sources that are not prohibited by legislation of the Russian Federation.

##### **Article 39. Emergency medical care**

Emergency medical care is rendered to citizens in conditions requiring urgent medical intervention (accidents, trauma, poisoning, other states and diseases), it is administered immediately by medical-preventive institutions, regardless of territorial or administrative subordination and nature of ownership, by health care workers, as well as individuals whose duty it is to render it as first aid according to law or special rule.



Emergency medical care is rendered by the special emergency medical care service of the State or municipal health care system following procedure established by the Russian Federation Health Ministry.

Emergency medical care is rendered to citizens of the Russian Federation and other individuals on its territory free of charge, and is funded by budgets on all levels.

When a citizen's life is threatened, health care workers have the right to free use of any available form of transportation to transport the citizen to the nearest medical-preventive institution. If an official or owner of the transportation refuses to execute the lawful demand of the health care worker for use of the vehicle to transport a victim, they bear responsibility as established by legislation of the Russian Federation.

#### **Article 40. Specialized medical care**

Specialized medical care is rendered to citizens with diseases that require special methods of diagnosis, treatment and use of complicated medical equipment.

Specialized medical care is rendered by specialists at medical-preventive institutions who are licensed in their specialty.

The type, scope and quality standards of specialized medical care rendered in institutions of the State or municipal health care system are established by the Russian Federation Health Ministry, health ministries of republics of the Russian Federation.

Specialized medical care is funded by budgets on all levels, special-purpose funds earmarked for public health care, citizens' personal resources and from other sources that are not prohibited by legislation of the Russian Federation. The different forms of specialized medical care, a list of which is defined annually by the Russian Federation Ministry of Health, are funded by the State health care system.

#### **Article 41. Socio-medical care of citizens with socially significant diseases**

Citizens with socially significant diseases, the list of which is defined by the Russian Federation Government receive sociomedical aid and are provided with clinical observation in appropriate medical-preventive institutions free of cost or on preferential terms.

The types and scope of socio-medical aid provided to citizens with socially significant diseases are established by the Russian Federation Health Ministry together with concerned ministries and departments.

The list and types of preferential terms in rendering sociomedical aid to citizens with socially significant diseases are established by the Supreme Soviet of the Russian Federation and Russian Federation Government, supreme soviets and governments of republics of

the Russian Federation, state and administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

Sociomedical care of citizens with socially significant diseases is funded by budgets on all levels, special-purpose funds earmarked for public health care, and other sources that are not prohibited by legislation of the Russian Federation.

#### **Article 42. Sociomedical aid of citizens with diseases presenting a hazard to others**

Socio-medical aid is free for citizens with diseases presenting a hazard to others, a list of which is defined by the Russian Federation Government, in institutions intended for this purpose in the State or municipal health care system.

The types and scope of socio-medical aid for citizens with diseases presenting a hazard to others are established by the Russian Federation Health Ministry and government committee for sanitary and epidemiological oversight of the Russian Federation, together with concerned ministries and departments.

For different categories of citizens with diseases presenting a hazard to others, jobs are saved for the duration of their temporary disability; preferential terms, housing and other benefits are provided as defined by the Supreme Soviet of the Russian Federation and Russian Federation Government, supreme soviets and governments of republics in the Russian Federation, state and administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

Socio-medical aid for citizens with diseases presenting a hazard to others is funded by budgets on all levels and other sources that are not prohibited by legislation of the Russian Federation.

#### **Article 43. Procedure for using new preventive, diagnostic, therapeutic methods, drugs, immunobiological agents and disinfectants, and biomedical research**

In health care practice, use is made of preventive, diagnostic and therapeutic methods, medical equipment, drugs, immunobiological agents and disinfectants that are allowed for use following procedure established by law.

Diagnostic and therapeutic methods, and drugs, which are prohibited but under consideration following established procedure, may only be used in the interests of curing a patient after obtaining his voluntary written consent.

Diagnostic and therapeutic methods, and drugs, which are prohibited but under consideration following established procedure, may be used to cure individuals under 15 years of age only if there is an immediate threat to their life and with the written consent of their legal representatives.



Procedure for using the diagnostic and therapeutic methods, drugs, immunobiological agents and disinfectants listed in the second and third parts of this article, including those used abroad, is established by the Russian Federation Ministry of Health or other authorized agencies.

Biomedical research is allowed in institutions of the State or municipal health care system and must be based on prior laboratory experiments.

All biomedical research involving man as its object can be carried out only after receiving the citizen's written consent. A citizen cannot be forced to participate in biomedical research.

Upon receiving consent to biomedical research, the citizen must be provided with information about the purposes, methods, side-effects, possible risk, duration and expected results of the study. The citizen has the right to refuse to participate in the study at any stage.

It is prohibited to publicize information, including use of mass media, about preventive, diagnostic, therapeutic methods and drugs that have not undergone trials following procedure established by law. Failure to abide by this law is subject to liability as established by legislation of the Russian Federation.

**Article 44.** Supplying drugs and medical items, immunobiological agents and disinfectants to the public

Production and purchase of drugs and medical items are provided in accordance with the needs of the public by the Russian Federation Government. Quality of drugs, immunobiological agents, disinfectants and medical items is monitored by the Russian Federation Health Ministry or other authorized ministries and departments.

The categories of citizens supplied with drugs and medical items for personal use on preferential terms are established by the Russian Federation Government and governments of republics of the Russian Federation. Attending physicians in the State, municipal and private health care systems have the right to write prescriptions for drugs on preferential terms.

**Article 45.** Prohibition of euthanasia

It is forbidden for health care workers to practice euthanasia, i.e., to grant a patient's wish to speed his death by any action or means, including interruption of artificial life-support measures.

An individual who deliberately suggests euthanasia to a patient and/or carries out euthanasia is subject to criminal liability in accordance with legislation of the Russian Federation.

**Article 46.** Definition of death

A health care worker (physician or feldsher) determines the occurrence of death.

The criteria and procedure for determination of the time of death, and cessation of resuscitation measures are established by statute approved by the Russian Federation Ministry of Health, in coordination with the Russian Federation Ministry of Justice, and health care ministries of republics in the Russian Federation.

**Article 47.** Removal of human organs and/or tissues for transplantation purposes

Removal of human organs and/or tissues for transplantation is allowed in accordance with legislation of the Russian Federation.

Human organs and/or tissues may not be subject to purchase, sale or commercial deals.

Compulsory removal of human organs and/or tissues for transplantation is prohibited.

Individuals involved in the said commercial deals, purchase and sale of human organs and/or tissues are subject to criminal liability in accordance with legislation of the Russian Federation.

**Article 48.** Conduct of autopsies

Autopsies are performed by physicians in order to gain information about cause of death and diagnosis of illness.

The procedure for conducting autopsies is determined by the Russian Federation Ministry of Health.

In the absence of suspicion of violent death, an autopsy is not conducted when there are religious or other grounds, if there is a written request by family members, close relatives or legal representative of the decedent, or if the decedent had expressed his wishes prior to death, unless otherwise stipulated in legislation of the Russian Federation.

The conclusion as to cause of death and diagnosis of illness is issued to family members and, in their absence, close relatives or legal representative of the decedent, as well as to legal protection agencies at their request.

Family members, close relatives or a legal representative of the decedent have the right to request a pertinent specialist who would agree to participate in the autopsy. An independent medical opinion may be obtained, following procedure stipulated in Article 53 of these Fundamentals, upon request of family members, close relatives, or legal representative of the decedent.

#### **Section IX. Expert Medical Opinions**

**Article 49.** Expert opinion on temporary inability to work

An expert opinion is provided, following procedure established by legislation of the Russian Federation, on inability to work due to illness, injury, pregnancy, parturition, care of sick family member, need for prostheses, sanatorium and resort therapy, and in other instances.

Expert determination of temporary inability to work is made by attending physicians in State, municipal and private health care systems, who personally issue disability certificates to citizens for up to 30 days, whereas for longer terms the disability certificates are issued by a medical commission appointed by the administrator of the medical institution.

In forming an expert opinion of temporary inability to work, determination is made of the need and duration of temporary or permanent transfer of the worker to another job for health reasons, and a decision is made about referral of the citizen, following established procedure, to a sociomedical commission, including cases when this citizen has signs of being disabled.

When writing up the disability certificate, in order to adhere to medical privilege, information about diagnosis is entered with the consent of the patient, otherwise only the cause of inability to work is given (illness, trauma or other reason).

In some cases, by decision of local health care administrative agencies, a midlevel health care worker may be asked to provide an expert opinion about inability to work in institutions of the State or municipal health care system.

#### **Article 50. Sociomedical expert opinion**

An expert sociomedical opinion establishes the cause and classification group of disability, extent of loss of ability to work of citizens, determines the types, scope and duration of rehabilitation and social protection measures, offers recommendations on employment. Expert sociomedical opinions are issued by institutions of sociomedical expertise in the system of social protection of the public.

It is mandatory for management of enterprises, institutions and organizations, regardless of nature of ownership, to follow expert sociomedical recommendations on citizen employment.

The procedure for organizing and providing an expert sociomedical opinion is established by legislation of the Russian Federation.

The citizen or his legal representative has the right to ask a specialist to participate, provided the latter agrees, in forming an expert sociomedical opinion.

The conclusion of the institution that obtains an expert sociomedical opinion can be appealed in court by the citizen himself or his legal representative following procedure established by legislation of the Russian Federation.

#### **Article 51. Expert military-medical opinion**

Military medical experts determine physical fitness for military service of citizens subject to the draft, enlistees, and reserves of the Armed Forces of the Russian Federation, federal State Security agencies and Border Troops

of the Russian Federation, and military personnel; for military personnel (and mobilized citizens) and those discharged from military service, they determine whether illness, wounds or trauma are related to military service (mobilization), determine types, scope and duration of socio-medical care of military personnel and their rehabilitation.

The procedure for organizing and providing expert military medical opinions, as well as health requirements for citizens subject to the draft, enlistees and military personnel are established by the Russian Federation Government.

Conclusions expressed in the expert military medical opinion are mandatory as to execution by officials on the territory of the Russian Federation.

Citizens have the right to obtain an independent military medical opinion following procedure stipulated in Article 53 of these Fundamentals.

The conclusion of the institution that obtains an expert sociomedical opinion can be appealed in court by the citizen himself or his legal representative following procedure established by legislation of the Russian Federation.

#### **Article 52. Forensic medical and forensic psychiatric expert opinions**

An expert forensic medical opinion is obtained in medical institutions of the State or municipal health care system, formed by an expert in the office of forensic medical expertise or, in his absence, by a physician called upon to give an expert opinion, on the basis of orders from the individuals carrying out the investigation, investigator, prosecutor, or court order.

An expert forensic psychiatric opinion is obtained in institutions of the State or municipal health care system designated for this purpose.

The citizen or his legal representative has the right to submit a petition to the agency that ordered the forensic medical or forensic psychiatric expert opinion for inclusion in the commission of experts of an additional specialist in the appropriate field, with consent of the latter.

The procedure for organizing and providing expert forensic medical and forensic psychiatric opinions is established by legislation of the Russian Federation.

The conclusions of institutions providing expert forensic medical and forensic psychiatric opinions may be appealed following procedure established by legislation of the Russian Federation.

#### **Article 53. Independent expert medical opinion**

If citizens disagree with the expert medical conclusion, an independent expert medical opinion is obtained upon

their request in the appropriate form, as stipulated in articles 43 and 41 of these Fundamentals.

An expert opinion is deemed independent when the expert or commission members who prepare it are not related either through work or other factor to the institution or commission that provided the expert medical opinion, as well as agencies, institutions, officials and individuals concerned with the results of independent expertise.

The statute on independent expert medical opinions is approved by the Russian Federation Government.

Citizens have the right to choose the expert institution and experts to provide an independent expert medical opinion. In case of dispute, the final decision as to conclusion of the medical experts is made by a court.

#### **Section X. Rights and Social Protection of Medical and Pharmaceutical Personnel**

##### **Article 54. Right to engage in health care and pharmaceutical work**

Individuals with higher or secondary medical and pharmaceutical education in the Russian Federation, those with diplomas and special title have the right to engage in health care and pharmaceutical work in the Russian Federation, and those with a specialist certificate and license have the right to engage in specific types of work, the list of which is established by the Russian Federation Ministry of Health.

A specialist certificate is issued on the basis of postgraduate professional education (internship, residency) or additional education (advanced training, specialization), or testing on theory and practice of chosen specialty, questions of legislation in the field of public health care, by commissions of professional medical and pharmaceutical associations.

During the period of instruction in institutions of the State or municipal health care system, physicians have the right to work in said institutions under the supervision of medical personnel responsible for their professional training. Students of higher and secondary medical educational institutions are allowed to participate in rendering medical care to citizens in accordance with instruction programs under the supervision of medical personnel responsible for their professional training following procedure established by the Russian Federation Health Ministry.

Individuals who have not completed higher medical or pharmaceutical education may be allowed to engage in medical or pharmaceutical work in the capacity of personnel with secondary medical education following procedure established by the Russian Federation Health Ministry.

Physicians or pharmacists who have not worked in their special field for more than five years may be allowed to practice medicine or perform pharmaceutical work after

retraining in appropriate educational institutions, or on the basis of testing carried out by commissions of professional medical and pharmaceutical associations.

Personnel with secondary medical or pharmaceutical education who have not worked in their special field for more than five years may be allowed to engage in medical or pharmaceutical work after confirmation of their qualifications in appropriate institutions of the State or municipal health care system, or on the basis of testing carried out by commissions of professional medical and pharmaceutical associations.

Individuals who received their medical and pharmaceutical training in foreign nations are allowed to engage in health care or pharmaceutical work after examination in appropriate educational institutions of the Russian Federation, following procedure established by the Russian Federation Government, as well as after receiving licenses to perform the types of work stipulated by the Russian Federation Ministry of Health, unless otherwise provided by international agreements of the Russian Federation.

Individuals illegally engaged in medical or pharmaceutical work bear criminal liability in accordance with legislation of the Russian Federation.

##### **Article 55. Procedure and conditions of issuing licenses for specific types of medical and pharmaceutical work**

Licenses for specific forms of medical and pharmaceutical work are issued to individuals by licensing commissions set up by the subject State administrative agency of the Russian Federation, or local administration at the request of the relevant subject State administrative agency of the Russian Federation.

Licensing commissions consist of representatives of health care administrative agencies, professional medical and pharmaceutical associations, higher medical educational institutions and institutions of State and municipal health care systems. Licensing commissions bear responsibility for validity of their decisions.

A license is issued for a specific form of work on the basis of a specialist certificate. There is a separate procedure for issuing licenses for another type of work.

The licenses of individuals engaged in specific types of medical and pharmaceutical work may be revoked or suspended by licensing commissions or by court decision, in the event that the work performed does not conform to established health care quality standards or regulations prescribed in these Fundamentals. Licenses are reinstated after relicensing upon disappearance of grounds for which the license was revoked or suspended. The decisions of licensing commissions may be appealed in pertinent State agencies and/or court.

Procedure and conditions for issuing licenses to individuals for specific types of medical and pharmaceutical work are established by the Russian Federation Government.

The list of types of medical and pharmaceutical work subject to licensing is established by the Russian Federation Ministry of Health.

#### **Article 56. Right to engage in private medical practice**

Private medical practice refers to rendering medical services by health care workers outside institutions of the State and municipal health care systems, at the expense of citizens' personal funds or funds of enterprises, institutions and organizations, including health insurance organizations, in accordance with existing contracts.

Private medicine is practiced in accordance with these Fundamentals and other legislative acts of the Russian Federation and republics of the Russian Federation.

Individuals who have received a diploma of higher or secondary medical education, a specialist's certificate and license for the chosen form of work have the right to practice private medicine.

Permission to practice private medicine is granted by local administration in coordination with professional medical associations and is in force within its subordinated territory.

The quality of medical care is monitored by professional medical associations and the local administration. The local administration cannot intervene in any other way in the activities of individuals who are in private practice, with the exception of instances where such intervention is directly stipulated by law.

The right to private medical practice can be prohibited by decision of the agency that granted permission for private medical practice or the court.

#### **Article 57. Right to practice folk medicine (healing)**

Folk medicine refers to methods of health improvement, prevention, diagnosis and treatment based on the experience of many generations of people, that have become firmly established in folk traditions and are not registered following procedure established by legislation of the Russian Federation.

Citizens of the Russian Federation who have received a healer's diploma, which is issued by health ministries of republics of the Russian Federation, health care administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, have the right to engage in folk medicine.

The decision to issue a healer's diploma is made on the basis of a citizen's application and presentation by professional medical association, or citizen's application and joint presentation by a professional medical association and institution licensed for the said type of work. The holder of healer's diploma has the right to practice folk medicine on the territory subordinated to the health care administrative agency that issued the diploma.

Individuals who have received a healer's diploma practice folk medicine following procedure established by the local administration in accordance with Article 56 of these Fundamentals.

Use of folk medicine methods is permitted in medical-preventive institutions in the State or municipal health care system by decision of administrators of said institutions, in accordance with Article 43 of these Fundamentals.

It is prohibited to conduct mass healing sessions, including use of mass media.

A healer's diploma can be revoked by decision of the health care administrative agency that issued said diploma, and said action can be appealed in court.

The illegal practice of folk medicine (healing) is subject to administrative liability, and to criminal liability in cases stipulated in legislation of the Russian Federation.

#### **Article 58. Attending physician**

The attending physician is the physician who renders medical care to a patient during the period of his observation and treatment in outpatient-polyclinical or hospital institutions. The attending physician may not be a physician undergoing training in a higher medical educational institution or postgraduate professional training institution.

The attending physician is appointed by the choice of the patient or administrator of a medical-preventive institution (or department thereof). If a patient demands replacement of the attending physician, the latter must cooperate in choosing another physician.

The attending physician organizes timely and qualified examination and treatment of the patient, furnishes information about his condition, invites consultants and organizes conferences of physicians at the request of the patient or his legal representative. Consultants' recommendations are followed only with consent of the attending physician, with the exception of emergency situations presenting a threat to the patient's life.

The attending physician personally issues disability certificates for terms of up to 30 days.

In cases where a patient does not follow instructions or rules of intramural procedure of the medical-preventive institution, the attending physician may, in agreement with the appropriate official, refuse to supervise and treat a patient provided the patient's life is not in danger and he does not present a danger to the health of others.

The attending physician bears responsibility for poor performance of his professional duties in accordance with legislation of the Russian Federation and republics of the Russian Federation.



#### Article 59. Family physician

The family physician is a physician who has undergone special training in many fields on primary medical and health care of family members regardless of their sex and age.

The procedure to be followed in the work of a family physician is established by the Russian Federation Ministry of Health and health ministries of republics of the Russian Federation.

#### Article 60. Physician's oath

Individuals who have graduated from higher medical educational institutions and received a physician's diploma take the physician's oath.

The text of the physician's oath is approved by the Supreme Soviet of the Russian Federation.

Physicians who break the physician's oath bear liability as established by legislation of the Russian Federation.

#### Article 61. Doctor-patient confidentiality

Information about seeking medical care, physical condition of a citizen, diagnosis of his disease and other information obtained from examination and treatment is privileged. The patient must have a confirmed guarantee of the confidentiality of information he furnishes.

For individuals who gain privileged information in training, performance of professional, business and other duties, it is prohibited to disseminate such information, with the exception of cases established in the third and fourth parts of this Article.

With the consent of a citizen or his legal representative, it is allowed to transmit privileged information to other citizens, including officials, in the interests of examination and treatment of the patient to carry out research, publish it in the scientific press, to use such information in the educational process and for other purposes.

It is permitted to furnish privileged information without the consent of a citizen or his legal representative in the following cases: 1) for the purpose of examination and treatment of a citizen unable to express his reasons because of his condition; 2) in cases of danger of spread of communicable diseases, mass scale poisoning and trauma; 3) at the request of inquiry and investigative agencies, prosecutor and court in connection with investigation or court hearing; 4) when rendering care to a minor up to 15 years old, to inform his parents or legal representatives; 5) in the presence of grounds to believe that the citizen was injured as a result of illegal acts.

Individuals who have received privileged information following procedure established by law, along with medical and pharmaceutical personnel, with consideration of the harm inflicted on a citizen, bear disciplinary, administrative or criminal liability for disclosing privileged information, in accordance with legislation of the Russian Federation and republics of the Russian Federation.

#### Article 62. Professional medical and pharmaceutical associations

Medical and pharmaceutical personnel have the right to create professional associations and other public associations formed on a voluntary basis to protect the rights of medical and pharmaceutical workers, develop medical and pharmaceutical practice, assist in research, solve other problems related to professional work of medical and pharmaceutical personnel.

Professional medical and pharmaceutical associations participate in: 1) elaboration of standards of medical ethics, decision of issues related to failure to meet said standards; 2) development of quality standards of medical care, federal programs and criteria for training and advanced training of medical and pharmaceutical workers, conferment of qualification categories to medical and pharmaceutical workers; 3) licensing medical and pharmaceutical work; 4) agreements on rates for medical services in the system of mandatory health insurance and activity of funds of mandatory health insurance.

Professional medical and pharmaceutical associations of republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg may conduct tests on medical and pharmaceutical workers in theory and practice of their chosen specialty, questions of legislation in the field of public health care, and issue the appropriate specialist certificate, as well as to offer suggestions on conferring qualification categories.

Professional medical, pharmaceutical and other social associations operate in accordance with legislation of the Russian Federation and republics of the Russian Federation.

#### Article 63. Social and legal protection of medical and pharmaceutical workers

Medical and pharmaceutical workers have the right to:

- 1) working conditions conforming to labor safety requirements;
- 2) have a labor agreement (contract) for their work, including work abroad;
- 3) protection of their professional honor and dignity;
- 4) obtaining a qualification category consistent with the level of their theoretical and practical training;
- 5) advanced professional training;
- 6) retraining funded by budgets on all levels when unable to perform professional duties for health reasons, as well as in cases of reduction in personnel or liquidation of enterprises, institutions and organizations;
- 7) insurance for professional mistakes resulting in harm or detriment to health unrelated to negligence or carelessness in performing their professional duties;
- 8) unimpeded and free use of transportation resources belonging to enterprises, institutions, organizations or



citizens, as well as any available form of transportation to transport a citizen to the nearest medical-preventive institution in death-threatening cases;

- 9) priority provision of housing, installation of a telephone, space for their children in preschool and sanatorium-resort institutions for children, acquisition on preferential terms of a motor vehicle for use in performing professional duties when work involves travel and other preferential treatment as provided by legislation of the Russian Federation and republics of the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

Physicians, pharmacists, midlevel medical and pharmaceutical personnel in the State and municipal health care systems who work and reside in rural areas and urban-type settlements, as well as family members residing with them, have the right to a free apartment with heat and electricity, in accordance with existing legislation.

The procedure for retraining and advanced training of medical and pharmaceutical personnel, assigning a qualification category is determined in accordance with these Fundamentals by the Russian Federation Ministry of Health, health ministries of republics of the Russian Federation, jointly with professional medical and pharmaceutical associations.

#### **Article 64. Wages and compensations**

Medical and pharmaceutical workers, as well as researchers, professorial and teaching staff of higher and secondary medical and pharmaceutical educational institutions, and medical departments of universities are remunerated for their work in accordance with their qualifications, tenure and duties they perform, as stipulated in the labor agreement (contract).

Medical and pharmaceutical workers have the right to compensatory payment, as percentage of regular wages, for working under deleterious, difficult and hazardous conditions, as well as other preferential treatment as stipulated in labor legislation of the Russian Federation, republics of the Russian Federation, legal acts of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

The list of categories of workers with the right to raises, allowances and payments in addition to their wages, as well as other forms of compensation and preferential treatment, is established by the Russian Federation Government in agreement with trade unions.

Procedure and conditions for payment of compensations and preferential treatment of researchers in the State and municipal health care systems, as well as professorial and teaching staff of higher and secondary medical and pharmaceutical educational institutions and medical departments of universities conform to procedure and conditions for payment of compensations and preferential treatment of medical and pharmaceutical workers.

Mandatory State personal insurance coverage in the sum of 120 times the regular monthly wages is set up for medical, pharmaceutical and other workers in the State and municipal health care systems, whose work involves a threat to their life and health, in accordance with the list of jobs involving a threat to life and health of workers that is approved by the Russian Federation Government.

In the event of harm to the health of medical and pharmaceutical workers in the performance of their job or professional duties, they are compensated in an amount and following procedure established by legislation of the Russian Federation.

In the event of death of workers in the State and municipal health care systems while performing their job or professional duties in the course of rendering medical care or carrying out research, families of the victims are given a lump-sum grant in an amount equal to 120 times the regular monthly wages.

The procedure and conditions of issuing lump-sum grants to set up housekeeping, as established for specialists who have graduated from agricultural educational institutions, extent to graduates of medical and pharmaceutical higher and secondary educational institutions when they arrive for work in an assigned rural medical-preventive institutions.

#### **Section XI. International Collaboration**

##### **Article 65. International collaboration in the field of health care of citizens**

The Russian Federation collaborates with other nations in the field of public health care on the basis of international agreements of the Russian Federation.

If rules other than those contained in these Fundamentals are established in an international agreement of the Russian Federation, the rules of the international agreement apply.

Agreements made within the framework of international collaboration in the field of public health care by health care administrative agencies, as well as enterprises, institutions and organizations, must not limit human and citizen rights and freedoms in the field of health care as stipulated in these Fundamentals and other legislative documents of the Russian Federation.

#### **Section XII. Liability for Inflicting Harm to Citizens' Health**

##### **Article 66. Bases for indemnification if harm is inflicted to citizens' health**

In cases where harm is inflicted to a citizen's health, the guilty parties are obliged to indemnify the victims in a sum and following procedure established by legislation of the Russian Federation.

If harm to the health of citizens is inflicted by a minor or individual deemed incompetent according to procedure established by law, liability conforms to legislation of the Russian Federation.

Harm inflicted to citizens' health as a result of environmental pollution is indemnified by the State, juridical or physical entity that inflicted the harm, following procedure established by legislation of the Russian Federation.

**Article 67.** Reimbursement of medical expenses of citizens who are victims of illegal acts

Claims for funds spent on medical care of victims of illegal acts are submitted to enterprises, institutions and organizations responsible for the inflicted harm to health, payable to institutions of the State or municipal health care systems who bore the expenses, or to institutions in the private health care system, if treatment was rendered in institutions of the private health care system.

Individuals who acted together in causing harm to citizen health bear joint responsibility for indemnification.

If harm to the health of citizens is inflicted by minors, indemnification is made by their parents or their substitutes, and in the case of such harm is inflicted by individuals deemed incompetent according to procedure established by law, indemnification is effected at the expense of the State in accordance with legislation of the Russian Federation.

The damage subject to indemnification is determined following procedure established by legislation of the Russian Federation.

**Article 68.** Liability of medical and pharmaceutical workers for violation of citizen rights in the field of health care

If citizen rights in the field of health care are violated as a result of poor performance of professional duties by medical and pharmaceutical workers so as to inflict harm or cause death, indemnification is provided in accordance with the first part of Article 66 of these Fundamentals.

Indemnification does not exempt medical and pharmaceutical workers from disciplinary, administrative or criminal liability in accordance with legislation of the Russian Federation and republics of the Russian Federation.

**Article 69.** Citizen right to appeal actions of state agencies and officials infringing upon their rights and freedoms in the field of health care

The actions of State agencies and officials infringing upon the rights and freedoms of citizens, as defined in these Fundamentals, in the field of health care can be appealed in superior State agencies, to superior officials or taken to court, in accordance with existing legislation.

### **Decree on Reexamination of Fundamentals of Russian Federation Legislation on Public Health**

937C0386B Moscow ROSSIYSKAYA GAZETA  
in Russian 18 Aug 93 p 7

[Decree No 5488-1 of the Supreme Soviet of the Russian Federation On Reexamination of Fundamentals of Russian Federation Legislation on Public Health Care, signed by R. I. Khasbulatov, chairman of the RF Supreme Soviet, on 22 Jul 93]

[Text]Whereby it has reexamined the Fundamentals of Russian Federation Legislation on Public Health Care returned by the president of the Russian Federation, the Supreme Soviet of the Russian Federation hereby decrees:

To adopt the Fundamentals of Russian Federation Legislation on Public Health Care with consideration of suggestions of the president of the Russian Federation.

### **Decree on Procedure to Put Into Effect the Fundamentals of Russian Federation Public Health Legislation**

937C0386C Moscow ROSSIYSKAYA GAZETA  
in Russian 18 Aug 93 p 7

[Decree No 5489-1 of the Supreme Soviet of the Russian Federation On Procedure to Put Into Effect the Fundamentals of Russian Federation Legislation on Public Health Care, signed by R. I. Khasbulatov, chairman of the RF Supreme Soviet, on 22 Jul 93]

[Text]The Supreme Soviet of the Russian Federation hereby decrees:

1. To make the Fundamentals of Russian Federation Legislation on Health Care effective as of the day of publication.

2. To consider the RSFSR Law "On Public Care," dated 29 July 1971, ineffective as of the time the said Fundamentals are in force.

3. To establish that when the said Fundamentals are put into effect, previously issued legislative acts in the field of public health care apply in those parts that do not contradict said Fundamentals.

4. Committees for legal reform and current legislation dealing with health care and social security of the Supreme Soviet of the Russian Federation, jointly with the Russian Federation Government, are to submit, by 1 October 1993, a draft law for amendments to legislative acts of the Russian Federation, related to adoption of the said Fundamentals before 1 October 1993, to the Supreme Soviet of the Russian Federation for its consideration.

5. The Russian Federation Government is to bring its decisions into line with the said Fundamentals, as well as implement revision and abolition by ministries, state committees and agencies of the Russian Federation of

their enforceable enactments that contradict the said Fundamentals before 1 January 1994.

6. The committee for health care and social security of the Supreme Soviet of the Russian Federation is to implement monitoring of adherence to this decree and, if necessary, offer pertinent suggestions to the Supreme Soviet of the Russian Federation.

### Revision of Health Insurance Law

#### Law on Amendments of the RSFSR Law on Public Health Insurance

937C0388A Moscow FEDERATSIYA in Russian No 48, 29 Apr 93 p 6

[Law No 4741-1 of the Russian Federation On Amendments of the RSFSR law "On Public Health Insurance in the RSFSR," signed by B. Yeltsin, president of the Russian Federation, on 2 Apr 93]

[Text]

**Article 1. Make the following amendments to the RSFSR law "On Public Health Insurance in the RSFSR" (VEDOMOSTI SYEZDA NARODNYKH DEPUTATOV RSFSR I VERKHOVNOGO SOVETA RSFSR, 1991, No 27, p 920):**

1. In the title and text of the "On Public Health Insurance in the RSFSR," replace "RSFSR" with "Russian Federation," in text of articles replace "krays, oblasts, autonomous okrugs and autonomous oblasts" with "autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg."

2. Use the following wording in the fourth part of Article 1:

"Mandatory health insurance is a component of State health insurance and provides all citizens of the Russian Federation with equal opportunity to receive medical care and drugs funded by resources of mandatory health insurance in the volume and on conditions conforming to programs of mandatory health insurance."

3. In the title and text of Article 3, add "voluntary" after the words "object" and "by object."

4. In the third part of Article 5, replace "Union republics" with "States."

5. In the first part of Article 6, delete "free."

6. In the title and text of Article 7, delete "of citizens of other Union republics and" and "citizens of other Union republics" and, respectively.

7. In the second part of Article 9, delete the second paragraph.

8. In Article 10:—delete "Union of the USSR" in the last paragraph of the first part;—use the following wording for the second part: "The financial resources of the State

and municipal health care systems and financial resources of the State system of mandatory health insurance are formed from these sources";

9. In Article 11:—use the following wording for the title of the Article: "Financial resources of the State and municipal health care systems";—use the following wording for the first part: "The financial resources of the State and municipal health care systems are earmarked for implementation of State policy in the field of public health care. The Russian Federation Government, governments of republics in the Russian Federation, State administrative agencies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg, local administrations determine the extent of funding of the State and municipal health care systems.";—delete the second part;—use the following wording for the first paragraph of the third part: "Financial resources of the State and municipal health care systems are used for:";—in the first sentence of the fourth part, delete "health care funds," and delete the second sentence.

10. Use the following wording for Article 12:

**Article 12. Financial resources of the State system of mandatory health insurance**

The financial resources of the State system of mandatory health insurance are formed by deductions of insurants for mandatory health insurance. Federal and territorial mandatory health insurance funds are established as independent nonprofit finance and credit institutions to implement State policy in the field of mandatory health insurance.

The federal mandatory health insurance fund is established by the Supreme Soviet of the Russian Federation and Russian Federation Government and it operates in accordance with legislation of the Russian Federation.

Territorial mandatory health insurance funds are established by the supreme soviets of republics of the Russian Federation and governments of republics of the Russian Federation, councils of people's deputies of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg and relevant executive agencies, and they operate in accordance with legislation of the Russian Federation and republics of the Russian Federation, enforceable enactments of autonomous oblasts, autonomous okrugs, krays, oblasts, cities of Moscow and St. Petersburg.

Mandatory health insurance funds are designed to accumulate financial resources for mandatory health insurance, provide financial stability of the State mandatory health insurance system and equalize the financial resources for its implementation.

The financial resources of mandatory health insurance funds are the State property of the Russian Federation, they are not included in budgets or other funds, and they cannot be withdrawn.

The procedure for collecting insurance premiums for mandatory health care is elaborated by the government of the Russian Federation and approved by the Supreme Soviet of the Russian Federation.

11. In Article 13:—in the first part, replace “into health care funds” with “to fund the State and municipal health care systems.”—add a third part to this article reading as follows: “Federal and territorial mandatory health insurance funds are exempt from income taxes pertaining to basic occupation.”

12. In the second part of Article 15, add the following second paragraph: “to perform work dealing with mandatory health insurance on a nonprofit basis;”

13. In Article 16, replace “by the RSFSR Ministry of Finance and its agencies” with “agencies of the Russian federal service for oversight of insurance activities.”

14. In article 17:—in the second part, replace “Insurance premiums” with “Payments”;—use the following wording for the fourth part: “The rate of insurance premiums for mandatory health insurance for enterprises, organizations, institutions and other business entities, regardless of forms of ownership, is set at a percentage of credited wages on all bases, and is approved by the Supreme Soviet of the Russian Federation.”;—delete the fifth part;—add a seventh part to the article reading as follows: “Social organizations for the disabled, enterprises, associations and institutions that are the property of said organizations, which were set up to implement their charter purposes, are exempt from paying premiums for mandatory health insurance.”

15. In the first part of Article 23, delete “between the health insurance organization and medical institution.”

16. Use the following wording for the first part of article 27:

“Financial sanctions are applied to enterprises, institutions, organizations and other business entities, regardless of forms of ownership, for refusing to register as payers of insurance premiums; for concealing or underestimating the sums from which insurance premiums should be withheld; for being delinquent in payments thereof. Payment of fines and/or default interest does not release the insurant from health insurance obligations. Federal and territorial mandatory health care funds apply the rules set by Russian Federation tax agencies for collecting delinquent taxes in order to implement mandatory collection of fines and/or default interest.”

**Decree on Reexamination of RF law on  
Amendments to RSFSR Law on Public Health  
Insurance in the RSFSR**

937C0388B Moscow FEDERATSIYA in Russian No 48,  
29 Apr 93 p 6

[Decree No 4742-1 of the Supreme Soviet of the Russian Federation on Reexamination of Russian Federation

Law “On Amendments to the Law ,On Public Health Insurance in the RSFSR,” signed by R. I. Khasbulatov, chairman of the RF Supreme Soviet, on 2 April 1993]

[Text]Whereby it has reexamined the Russian Federation Law “On Amendments to the RSFSR Law”, “On Public Health Insurance in the RSFSR,” returned by the president of the Russian Federation, the Supreme Soviet of the Russian Federation hereby decrees:

To adopt the Russian Federation law “On Amendments to the RSFSR Law”, “On Public Health Insurance in the RSFSR,” with consideration of the suggestions of the president of the Russian Federation.

**Decree on Procedure to Put Into Effect the RF  
Law on Amendments to the RSFSR Law on  
Health Insurance**

937C0388C Moscow FEDERATSIYA in Russian  
No 48, 29 Apr 93 p 6

[Decree No 4743-1 of the Supreme Soviet of the Russian Federation on Procedure to Put Into Effect the Russian Federation Law “On Amendments to the RSFSR Law “On Public Health Insurance in the RSFSR,” signed by R. I. Khasbulatov, chairman of the RF Supreme Soviet, on 2 April 1993]

[Text]The Supreme Soviet of the Russian Federation hereby decrees:

1. To make the Russian Federation Law “On Amendments to the RSFSR Law” to “On Public Health Insurance in the RSFSR” effective as of the day of its publication.

2. The Russian Federation Government will:—bring the existing enforceable enactments dealing with public health insurance into line with the said Law and implement their execution before 15 April 1993;—implement revision and abolition by ministries and agencies of the Russian Federation of enforceable enactments they previously passed that are in contradiction with the said Law before 25 April 1993.

**Instructions on Registration of Potentially  
Hazardous Chemical and Biological Substances**

Moscow ROSSIYSKIYE VESTI in Russian No 124,  
1993 pp 4-5

[Instructions on Registration of Potentially Hazardous Chemical and Biological Substances, approved by V. I. Danilov-Danilyan, minister of environmental protection of the RF as No 37-2-7/435, dated 25 May 1993, and by Ye. N. Belyayev, chairman of the State Committee for Sanitary and Epidemiological Oversight as No 01-19/22-22, dated 25 May 1993; registered with the RF Ministry of Justice, registry No 279, on 18 July 1993]

[Text]



## 1. General Statutes

1.1. These instructions were prepared to implement Decree No 869 of the Russian Federation, dated 12 November 1992, "On State Registration of Potentially Hazardous Chemical and Biological Substances" and in accordance with the Statute on State registration of potentially hazardous chemical and biological substances, which was adopted in the said Decree.

1.2. State registration of potentially hazardous chemical and biological substances (hereafter referred to as State registration) is performed to implement the requirements in articles 12, 13, and 14 of the Russian Federation Law on Sanitary and Epidemiological Welfare of the Public, and articles 51 items 2 and 3 of the Russian Federation Law "On Environmental Protection."

1.3. State registration is implemented in a Russian Register of potentially hazardous chemical and biological substances (hereafter referred to as Register) for detection, accumulation of physicochemical, toxicological, ecotoxicological and other information, record-keeping and regulation of said substances in order to prevent their deleterious effects on human health and the environment.

1.4. An individual naturally occurring or synthetic substance (compound) that can have a deleterious effect on human health and the environment, when produced, used, transported, processed, as well as in household use, is considered a potentially hazardous chemical and/or biological substance.

1.5. All individual chemical and biological substances (compounds), including those contained in mixtures, produced and/or used on the territory of the Russian Federation, as well as imported substances, are subject to State registration.

Substances containing impurities formed in the production process or when used are registered as individual substances.

1.6. Compound commercial chemicals, which must undergo hygienic certification in accordance with Decree No 1, dated 5 January 1993, of the Goskomsanepidnadzor [Russian State committee for sanitary and epidemiological oversight], are not subject to State registration.

1.7. The procedure for State registration established in these Instructions does not extend to chemical and biological agents used to protect plants, farm crop and tree plantation growth regulators, pharmaceutical preparations, as well as radioactive substances, which are recorded or registered following previously established procedure by pertinent organizations.

1.8. Chemical and biological substances intended for production and use after 31 March 1993 ("new substances") are subject to registration prior to production and use.

Substances produced, used and processed on the territory of the Russian Federation, as well as imported, prior to 31 March 1993 ("old substances"), are subject to mandatory State registration within three years from the time of publication of these instructions. Specific registration dates must be coordinated with agencies of State sanitary oversight before 1 July 1993.

## 2. Procedure for State Registration

2.1. Chemical and biological substances (compounds) are registered when submitted by ministries, agencies, enterprises, organizations, institutions, other juridical entities, as well as individuals responsible for production and import of a given substance (compound), regardless of forms of ownership.

2.2. The registration process includes receiving applications, examining them and making the decision to register, and issuing a registration certificate.

2.3. The "List of information needed for State registration of potentially hazardous chemical and biological substances," which is filled out by the applicant who is responsible for accuracy of furnished data, is the basis for registration.

2.4. Substances for which complete information could not be submitted at the time of registration, but the properties and area of application of which warrant belief that its hazard to man and the environment is immaterial, are subject to registration for a term of 3 years with assignment of a State registration number and issuance of registration certificate with annotation of the 3-year validity. Fullness (or lack of necessity to submit data for some parameter or other) of submitted information is determined in each specific instance by the Register in accordance with existing standard-setting and methodological documentation.

If an applicant does not submit the necessary information within 3 years, as stipulated in the certificate, the registration certificate is no longer valid.

2.5. In the Register, there is a permanent group of experts, which is confirmed following established procedure, representing institutions of the Goskomsanepidnadzor of the Russian Ministry of Environmental Protection examines the most difficult cases related to making decisions on State registration of potentially hazardous chemical and biological substances.

2.6. Assignment to a chemical and biological substance of a State registration number and issuance of a registration certificate confirm the adequacy and quality of ecotoxicological and other parameters, and serve as grounds to enter them in standards and specifications documentation (NTD, such as GOST, TU and others) in the sections "Safety requirements" and "Environmental protection."



2.7. The finding as to conformity of specific production and use conditions for a substance with a State registration number to environmental protective and sanitary rules, adequacy of methods of assaying substances and conformity to NTD (GOST, TU, and others), as well as hygienic certification, are implemented by agencies of State sanitary and epidemiological oversight and Ministry Environmental Protection of the Russian Federation in accordance with sanitary and environment protective legislation.

2.8. Assignment of a State registration number and issuance of registration certificate are implemented on the basis of the expert finding of the Register's specialists and its approval by the director of the Register.

2.9. When registering a substance, the applicant remits payment in advance to the Register in accordance with the Statute approved by Decree No 552 of the Russian Federation Government dated 5 Aug 92, as well as for upgrading performance and material-technical support of the system of State registration of potentially hazardous chemical and biological substances.

2.10. Applications for State registration are addressed in the name of the Register's director at 101479 Moscow, Vadkovskiy Lane, 18-20.

2.11. Documentation for registration must include:

2.11.1. a referral (cover letter) signed by an enterprise administrator or individual entrepreneur;

2.11.2. filled out "List of information needed for State registration of potentially hazardous chemical and biological substances" (Appendix 1);

2.11.3. materials, on the basis which the "List of information...." was filled out;

2.11.4. payment authorization to pay for the registration fee;

2.11.5. official conclusion of the applicant as to possible publication of State registration materials in the free press.

2.12. Registration materials are to be examined within 30 days. After assignment of a registration number, the Register issues a certificate of State registration of the established specimen (Appendix 2) and information form (Appendix 3) to the applicant, and publishes information about registration in the Register's information bulletin.

2.13. Validity of a registration certificate can be suspended by the Register if new data are received concerning previously unknown hazardous properties of a substance. The Register notifies the applicant of suspension of the registration certificate and/or ban on the substance within 10 days of making this decision, and publishes this information in the Register's information bulletin.

2.14. The Register guarantees confidentiality of information about a substance that is an industrial secret unless it poses a threat to human health and environmental safety.

2.15. The Register may, under specific conditions, rightfully refuse to issue a registration certificate.

2.16. An appeal of the Register's decision must be filed, no later than 30 days after it is made, with the chairman of the Russian Goskomsanepidnadzor. The appeal is examined within 30 days. The decision of the chairman of the Russian Goskomsanepidnadzor may be appealed in Arbitration Court.

2.17. Enterprises and other business entities, regardless of the agency to which they pertain and form of ownership, organizations and institutions situated on the territory of the Russian Federation, individuals carrying out development, production and use, export and import of potentially hazardous chemical and biological substances bear responsibility in accordance with the "Statute on State registration of potentially hazardous chemical and biological substances," approved by Decree No 869 of the Russian Federation Government dated 12 November 1992.

**Appendix 1 1. State Committee of Sanitary and Epidemiological Oversight of the Russian Federation  
2. Ministry of Environmental Protection of the Russian Federation  
3. Russian Register of Potentially Hazardous Chemical and Biological Substances**

**List of Information Needed for State Registration of Potentially Hazardous Chemical and Biological Substances**  
1. Chemical name of substance (UPAC) 2. Molecular formula 17 3. Molecular (atomic) mass 4. Structural formula Synonyms 5. Trade name NTD  
Registration numbers according to: CAS 30 RTECS  
Purity of substance: 20 % Admixtures (name and amount) 30 30 % 60 %

1. Physicochemical parameters 1.1. Physical state (at 20°C, 760 mm Hg) 15 Solid 25 Liquid 25 Gas 1.2. Boiling point 35 °C 1.3. Melting point 35 °C 1.4. Density 35 g/cm<sup>3</sup> 25 g/l 1.5. Solubility in water and oils 1.6. Miscibility (substance, water) at 20°C 1.7. pH 25 at concentration of 10 mg/l water 1.8. Odor: 1.9. Reactivity 1.10. Manufactured form

2. Conditions of safe storage and handling, transportation and use

3. Toxicity

3.1. Acute toxicity (oral, inhalation, dermal)

3.2. Cumulative properties

3.3. Clinical signs of acute poisoning

3.4. Most vulnerable organs and systems

3.5. Minimal active dose (concentration)

3.6. Irritation

- 3.7. Dermal absorption
- 3.8. Sensitization
- 3.9. Embryotropic action
- 3.10. Gonadotropic action
- 3.11. Mutagenic action
- 3.12. Carcinogenic action

#### 4. Hygienic standards and classes of hazard (according to PDK /OBUV

#### 5. Method of identification (guidelines, sensitivity, NTD for technique) 5.1. In air of work zones

- 5.2. In atmosphere of populated areas
- 5.3. In water
- 5.4. In other environmental objects

#### 6. First aid for poisoning

#### 7. Ecological safety

- 7.1. Stability under abiotic conditions (1/2t)
- 7.2. Transformation in the environment
- 7.3. Biological disassimilation BD = BPK5/KhPK x 100%
- 7.4. Total BPK 40 mg O/dm<sup>3</sup>
- 7.5. KhPK 40 O/dm<sup>3</sup>
- 7.6. Acute toxicity in fish
- 7.7. Acute toxicity in *Daphnia magna* fleas
- 7.8. Toxic effect on algae (in culture)
- 7.9. PDK(ODU) in fisheries 20 mg/l
- 7.10. Toxic effect on soil invertebrates
- 7.11. Effects demonstrated in model and naturally occurring ecosystems

#### 8. Additional information

#### 9. Sources of Information

Applicant Date 20 199

[Stamp:] Exclusively for RV

#### Appendix 2. State Committee of Sanitary and Epidemiological Oversight of the Russian Federation Ministry of Environmental Protection of the Russian Federation Russian Register of Potentially Hazardous Chemical and Biological Substances

#### Certificate of State Registration of Potentially Hazardous chemical and Biological Substances

40 No 40 State registration number 40 " 3" 10 199  
Issued to 30 (applicant) It is hereby certified that 25  
(chemical name according to IUPAC) 25 (CAS No) 25  
(synonyms) 25 (trade name) 25 (area of application)

is registered in the Russian Federation Certificate is valid  
for 40 Director of Register 40 Place for seal

#### Appendix 3 State Committee of Sanitary and Epidemiological Oversight of the Russian Federation Ministry of Environmental Protection of the Russian Federation Russian Register of Potentially Hazardous Chemical and Biological Substances Information Form for Potentially Hazardous Chemical and Biological substances

Chemical name of substance (IUPAC) Molecular  
formula 30 Molecular mass Structural formula Syn-  
onyms Trade name NTD 27 Registration numbers  
according to: 25 CASn/40 RTECS Area of application  
Organizations that performed toxicological, hygienic  
and ecological evaluation, their addresses and telephone  
numbers

Purity of substance 20 % Admixtures (name and  
amount) [6]0 % 30 % 30 %

#### 1. Physicochemical parameters

- 1.1. Physical state (at 20°C, 760 mm Hg) 15 Solid 25  
Liquid 25 Gas 1.2. Boiling point 35 °C
- 1.3. Melting point 35 °C
- 1.4. Density 35 g/cm<sup>3</sup> 25 g/l
- 1.5. Solubility in water 25 soluble (mg/l) 25 insoluble  
25 20°C [2]5 °C [2]0 in oils
- 1.6. Miscibility (substance, water) 3 20°C
- 1.7. pH 25 at concentration of 10 mg/l water
- 1.8. Odor: 5 strong 5 marked[5] mild 5 none
- 1.9. Reactivity
- 1.10. Manufactured form
- 1.11. Additional information

#### 2. Storage and use conditions

- 2.1. Special precautionary measures during transporta-  
tion, storage and handling
- 2.2. Incompatibility with following substances
- 2.3. Hazardous dissociation products

2.4. Personal safety equipment: 3 Gas mask 3 Goggles 3 Gloves 3 Other 2.5. Measures in decanting and pouring

2.6. Utilization

### 3. Flammability and combustibility

3.1. Flash point <10 °C

3.2. Temperature range of flame 20 °C

3.3. Concentration range of flame 20 % vol.

3.4. Possibility of thermal degradation 10 yes/no 5 products formed

3.5. Means of quenching: 3 Water 3 CO<sub>2</sub> 3 Foam 3 Dry powder 3 Other

3.6. Special fire-prevention and explosion-prevention measures

### 4. Toxicity

4.1. Acute toxicity 5 LD<sub>50</sub> (mg/kg) 5 Route 5 Animal species 15 LC<sub>50</sub>(mg/m<sup>3</sup>) 5 Exposure time (h) 5 Animal species 4.2. Cumulative effect 10 Strong 10 Moderate 10 Mild

4.3. Clinical signs of acute poisoning

4.4. Most vulnerable organs and systems

4.5. Doses (concentrations) with minimal toxic effect (threshold, size, route and time of intake, animal species)

4.6. Irritation 10 skin 10 yes/no 10 eyes 10 yes/no

4.7. Dermal absorption 5 yes 5 TL<sub>50</sub> 5 no 5 not studied

4.8. Sensitization 5 yes 5 no 5 not studied

4.9. Embryotropic action 5 yes 5 no 5 not studied

4.10. Gonadotropic action 5 yes 5 no 5 not studied

4.11. Mutagenic action 5 yes 5 no 5 not studied

4.12. Carcinogenic action in man: 5 yes 5 no 5 not studied n[2]0 in animals:n[5] mild 5 moderate 5 strong 5 not studied

### 5. Hygienic standards\*

5 PDK/OBUV 5 PDK/OBUV 5 PDK/ODU 5 MDU 5 PDK/ODK 5 (air) 5 (work zone) 3(water) 5 (food) 5 (soil) m.r. 10 mg/m<sup>3</sup> 5 m.r. 10 mg/m<sup>3</sup> 7 mg/l 7 mg/kg 7 mg/kg s.s. 10 mg/m<sup>3</sup> 5 s.s. 10 mg/m<sup>3</sup>

6. Classes of hazard (according to PDK) 10 atmospheric air 10 work zone air 10 water

### 7. Method of determination

7.1. Principle involved, sensitivity, NTD for method\*\*

### 8. First aid for poisoning

### 9. Ecological safety

9.1. Stability under abiotic conditions (1/2t): 4>30 days 8 30x7 days 4 7x1 d 5 >1 hour and 5 <1 d> 1 h extremely stable 3 very stable 4 stable 3 somewhat stable 3 unstable

9.2. Transformation in the environment: 10 none 10 is transformed 10 transformation products

9.3. Biological disassimilation BD = (BPK<sub>s</sub>/KhPK) x 100% 30 >90% (complete) 30 50x90% (mild) 30 20x50% (insignificant) 30 10x20% (difficult) 30 <10% (does not break down)

9.4. Total BPK 40 mg O/dm<sup>3</sup>

9.5. KhPK 40 O/dm<sup>3</sup>

9.6. Acute toxicity in fish 3 LC<sub>50</sub> (mg/l) 5 species 5 Exposure time (hours)

9.7. Acute toxicity in *Daphnia magna* [water fleas]: 20 LC<sub>50</sub> (mg/l) 12 Exposure time (hours)

9.8. Toxic effect on algae (in culture): 20 LC<sub>50</sub> (mg/l) 12 Exposure time (hours)

9.9. PDK(ODU) in fisheries 20 mg/l

9.10. Toxic effect on soil invertebrates: 20 LC<sub>50</sub> (mg/l) 12 Exposure time (hours)

9.11. Effects demonstrated in model and naturally occurring ecosystems

### 10. Additional Information

### 11. Sources of Information

Footnotes: \*Underline standard corresponding to its meaning. \*\*Area of application of method.

[Stamp:] Exclusively for RV

[Key: BPK - biological oxygen requirement; LC - lethal concentration (?); KhPK - chemical oxygen requirement; m.r. - expansion unknown; MDU - maximum permissible level; NTD - standards and specifications documentation; OBUV - safe level in air?; ODK - total permissible concentration?; ODU - total permissible level ?; PDK - maximum permissible concentration; RV - Substance Register; s.s. - expansion unknown; TL - expansion unknown; TU - specifications]

### Russian Federation AIDS Program

937C0393A Moscow ROSSIYSKIYE VESTI in Russian No 147, 3 Aug 93 p 6

[Article: "Special-Purpose 1993-1995 Federal Program to Prevent the Spread of AIDS in the Russian Federation (AIDS Control)"]

[Text]

### Goals and Tasks

The main goal of this program is to prevent the spread of AIDS in the Russian Federation, lower socioeconomic consequences of AIDS by means of coordinated implementation of an aggregate of organizational, scientific and practical measures.

These measures will be implemented in the following directions:—prevention of sexual and blood transmission of AIDS;—diagnosis, treatment and screening;—legal and social safeguards;—refinement of epidemiological oversight system;—research on the AIDS problem;—furnishing information and personnel personnel.

### Prevention of Sexual Transmission of AIDS

For the next few years, sexual contact will remain as the principal route for the spread of AIDS. For this reason, it is imperative to establish a system of purposeful information of the public about the AIDS problem and increasing danger of acquiring this infection, and providing to the public available means of preventing sexual transmission of this infection.

The information must be understandable for different age and social groups. There are plans for: organization of topical radio and television transmissions, 25 video clips, 5 cinevideo and 5 video films, with organization of their screening in movie houses, translation and demonstration via State, agency and commercial radio and television channels; preparation and large-volume publication, as well as dissemination of educational materials (15 million flyers, 1 million posters and 5 million booklets per year), preparation of 5 general educational programs for sex and moral education for different age groups, their introduction in preschool institutions, general, vocational, secondary specialized and higher educational institutions; enlisting young people, religious and social organizations, leaders and activities in high-risk groups to participate in this work; expansion of the network of anonymous screening and psychological support offices, and organization of such offices in cities with a population of more than 200,000; performance of systematic sociological studies of the AIDS problem.

In order to provide a sufficient number of contraceptives at an affordable price, it is planned to expand their manufacture at Russian Federation enterprises and to issue them to specific population groups among those with high risk of infection (drug addicts, individuals living in dormitories, etc.).

It is assumed that the intensity of sexual transmission of the virus of immune deficiency will be lowered by 25-30 percent by 1996, as a result of implemented measures. Accordingly, there will be a reduction in cost of treating AIDS patients (in 1989, the cost per patient was 40,000 rubles, and in 1992 prices 500,000 rubles).

The principal executors of this section are:—Russian Federation Ministry of Health;—State Committee for

Sanitary and Epidemiological Oversight;—Russian State Television and Radio Broadcasting Company;—Russian Federation Ministry of Education;—Russian Federation Ministry of Internal Affairs;—Russian Federation Ministry of Culture;—Russian Federation Committee for Cinematography;—Russian Federation Ministry of the Press and Information;—Russian Federation Ministry of Justice;—Russian Federation Committee for the Chemical and Petrochemical Industry;—Russian Federation Ministry of Economics;—Russian Federation Ministry of Finance;—Russian Federation Committee for Tourism.

### Prevention of AIDS Transmission through Blood

The program provides for outfitting pertinent laboratories with equipment and diagnostic test systems, on the basis of the need to make 6 million tests per year, in order to upgrade the system of supplying safe blood, other biological materials and medical immunobiological preparations. In addition, it is planned to exclude by 1995 placental and abortion-related blood as raw material for the production of medical immunobiological preparations and change to use solely of donor blood for this purpose.

In view of the danger of potential intramural AIDS infection, there is a set of steps aimed at training medical personnel to ensure sanitary and epidemic-control conditions, expand and update the manufacture of syringes, needles, catheters and blood-transfusion systems that could cause infection of the blood via blood. Due consideration was also given to the fact that supplying medical-preventive [medical and preventive care] institutions with other types of disposable and reusable medical instruments, that come in contact with blood is covered by the State program of the Russian Federation for development of modern medical equipment and increasing production thereof in 1992-1993, and for the period up to 1995, which was approved by Decree No 77 of the government of the Russian Federation, dated 10 February 1992, "On urgent steps to develop modern medical equipment and increase its production in 1992-1995." The program also includes matters of furnishing medical-preventive institutions with sterilization equipment.

Fulfillment of the above volume of work would provide a reliable level of safety of donor blood and blood preparations, as well as medical procedures carried out at medical-preventive institutions by 1996.

The principal executors of this section are:—Russian Federation Ministry of Health;—State Committee for Sanitary and Epidemiological Oversight;—Russian Federation Ministry of Internal Affairs;—Russian Federation Committee for the Chemical and Petrochemical Industry;—Russian Federation Ministry of Finance;—Russian Federation Ministry of Economics.



### Diagnosis, Treatment and Screening

AIDS detection in medical-preventive and sanitary-epidemiological institutions will be carried out with use of screening and corroborative diagnostic preparations, equipment for enzyme immunoassay and polymerase chain reaction (gene amplification method), at the rate of the need for 4 million tests per year when clinically indicated and for screening high-risk groups.

It is planned to provide effective agents for the treatment of patients with AIDS and opportunistic infections that are not included in the list of vitally necessary drugs adopted by the decree of the government of the Russian Federation dated 26 December 1991 "On urgent measures to provide the public and RSFSR health care institutions with drugs in 1992 and to develop the pharmaceutical industry in 1992-1995."

Treatment of AIDS patients will be administered at the Russian Republic Center for AIDS Prevention and Control in the city of Moscow, and at the clinical infectious-disease hospital in St. Peter-burg, where all types of specialized medical care are rendered to them, as well as terminal patient care. Treatment and screening of HIV-positive individuals and AIDS patients will also be carried out by territorial centers for the prevention and control of AIDS and medical-preventive institutions in the area of their residence. Offices for medicopsychological counseling are being organized in centers for AIDS prevention for individuals with this pathology, their families, as well as those in high-risk groups. Specialized centers are being opened for children who are HIV-positive and have AIDS.

It is also planned to set limits on State capital investments for construction and reconstruction of infectious-disease hospitals, centers for AIDS prevention and control, laboratories for AIDS detection and Gossanepidnadzor [State Committee for Sanitary and Epidemiological Oversight] centers.

Implementation of these measures will have a social impact by 1996 with respect to this category of individuals, by extending the period of their ability to work and prolonging their lives by 2-3 years.

The principal executors of this section are:—Russian Federation Ministry of Health;—State Committee for Sanitary and Epidemiological Oversight;—Russian Federation Ministry of Economics;—Russian Federation Ministry of Finance.

### Legal and Social Safeguards

The program provides for preparation of a draft law of the Russian Federation "On AIDS Prevention," which will reflect matters of legal protection of HIV-positive individuals and AIDS patients, as well as matters of legal and social protection of health care workers exposed to the risk of this infection.

There are plans for the following:—legislate steps precluding discrimination against the sick and infected;—

payment of State benefits to individuals infected during medical procedures;—free testing, treatment and upkeep of HIV-positive individuals and AIDS patients in health-care institutions;—free travel of these individuals to and from place of treatment;—priority provision of isolated housing for individuals infected during medical manipulations, as well as families with infected children up to 16 years old;—education of children and adolescents undergoing hospital care.

There are also provisions for saving jobs for HIV-positive individuals and AIDS patients for the duration of their testing and treatment, with the exception of health-care workers involved in their jobs in carrying out parenteral procedures. Job placement is provided for this category of health-care personnel.

As a result of implementing these measures, the legal relationships will be regulated between the State, medical institutions, HIV-positive individuals and AIDS patients, as well as individual juridical entities, which will provide for social and legal protection of HIV-positive individuals and AIDS patients, as well as health-care workers and other categories of the public.

The principal executors of this section are:—Russian Federation Ministry of Social Protection of the Public;—Russian Federation Central Committee of the Health-Care Workers Trade Union;—Russian Federation Ministry of Labor;—Russian Federation Ministry of Justice;—Russian Federation Ministry of Health;—State Committee for Sanitary and Epidemiological Oversight;—Russian Federation Ministry of Economics;—Russian Federation Ministry of Finance.

### Refinement of Epidemiological Oversight System

It is planned to elaborate a better system of epidemiological oversight for AIDS, including organization of monitoring of HIV-positive and high-risk groups for this infection, laboratory test findings and dates for such tests, reliable methods of short- and long-term forecasts of development of an epidemic process. There will be continued supply of computer hardware and software to centers for AIDS prevention and centers of the State Committee for Sanitary and Epidemiological Oversight, as well as telecommunication equipment, which will permit establishment of a unified and integrated, automated information-analyzing system on this problem, based on basic computer programs on the federal and regional levels. There will be a revision and improvement of the system of medical certification of the public, which calls for the change from large-volume, epidemiologically and economically unwarranted tests to testing samples of different population categories and retention of the volume of tests for individuals in high-risk and other groups.

By 1996, these measures will permit achieving higher effectiveness in detecting sources of infection and pinpointing sites of the disease, with concurrent reduction by 10-15 million tests in volume of screening the public. With one test costing 50 rubles (in 1992 prices), these

steps will save 500 million rubles. Epidemiological and mathematical models will be developed to provide high-level forecasting of epidemics and related economic expenses.

The principal executors of this section are:—State Committee for Sanitary and Epidemiological Oversight—Russian Academy of Medical Sciences;—Russian Federation Ministry of Health;—Russian Federation Ministry of Finance;—Russian Federation Ministry of Economics.

### **Research on the AIDS Problem**

There is insufficient funding of research on the AIDS problem. This program provides for carrying out research on isolation and identification of viruses of human immune deficiency, investigation of their biological properties, mechanisms of interaction with cells in the body and onset of immunodepression in HIV-positive individuals and AIDS patients, refinement and development of new diagnostic methods, optimum treatment programs, search for new compounds and products with specific activity, investigation of epidemiology of AIDS, development of specific prophylactic agents, methods of inactivating the virus in donor material and blood preparations, methods of protecting health-care personnel, investigation of distinctions of the epidemiological process with AIDS in different territories, research aimed at further investigation of symptomatology of HIV infection.

Research will be carried out within the framework of the State research program of the Russian Federation, "National priorities in medicine and health care" (Section 6 "AIDS"). Formulation of topics in this direction is done annually on the basis of competition, with expert evaluation of submitted projects.

The principal executors of this section are:—Russian Academy of Medical Sciences;—State Committee for Sanitary and Epidemiological Oversight;—Russian Federation Ministry of Health;—Russian Federation Ministry of Finance;—Russian Federation Ministry of Economics.

### **Furnishing Information and Personnel Training**

The social importance of the the AIDS problem makes it necessary to have highly trained personnel to implement organizational, therapeutic, prophylactic and epidemic-control measures and to furnish them with information.

In this regard, there are plans to do the following:—add matters of AIDS prevention to the syllabus of secondary general educational, vocational, secondary specialized and higher educational institutions;—train physicians and pedagogues at institutes for advanced training and courses for advancement, and specialists in sociopsychological counseling of HIV-positive individuals and AIDS patients at the Republic Institute for Advanced Training of Educators and its affiliates;—train leaders for youth

organizations and activists in high-risk groups at territorial centers for AIDS prevention;—train researchers and clinical health-care specialists in the leading specialized research institutions of the Russian Federation (50 people per year) and abroad (5 per year).

It is also planned to publish relevant scientific and educational literature (monographs, topical surveys, collections, textbooks, guides, etc.) and to subscribe to the entire system of health care, education and information with AIDS.

These measures will make it possible to train highly qualified personnel to administer specialized medical care and, at the same time, improve efficiency of the entire system of health care, education and information on this problem.

The principal executors of this section are:—State Committee for Sanitary and Epidemiological Oversight;—Russian Federation Ministry of Health;—Russian Academy of Medical Sciences;—Russian Federation Ministry of the Press and Information—Russian Federation Ministry of Economics;—Russian Federation Ministry of Finance.

### **Management and Mechanism of Implementation of the Program**

The effectiveness of implementation of this program will depend largely on constant and integral evaluation of its progress and subsequent correction (if necessary).

For this purpose, there are the following provisions, to:—appoint program administrators and organize coordinating councils on the federal and regional levels;—carry out independent integral evaluation of research and measures, with appropriate correction of the program.

The program will be implemented through the existing network of AIDS-prevention institutions and the State Committee for Sanitary and Epidemiological Oversight, on the basis of work plans of executor organizations. There are also plans to develop and implement regional programs with approval of their funding in pertinent State agencies of republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

It is planned to implement international collaboration with the World Health Organization, within the framework of the global program for AIDS control, and other international organizations.

Funding of this program from the federal budget is provided in an amount of 12.42 billion rubles and \$20.85 million, including 6.52 billion rubles and \$8.25 million in 1993. Of these amounts, limits of State centralized capital investments funded by the federal budget and investment credit will constitute 4.1 billion rubles for 1993.

According to estimates, 96.8 billion rubles, including 32.24 billion for 1993, will be needed to implement measures to provide medical-preventive institutions of the Russian Federation with medical instruments (reusable syringes and needles, disposable catheters), sterilizers and laboratory equipment protective gear for medical personnel, social and legal protection of HIV-positive individuals and AIDS patients.

The functions of State contractors are delegated to the State Committee for Sanitary and Epidemiological Oversight and Russian Federation Ministry of Health.

### **Russian Law on Donating Blood and Its Components**

#### **Law of the Russian Federation on Donating Blood and Its Components**

937C0395A Moscow ROSSIYSKAYA GAZETA  
in Russian 10 Jul 93 p 10

[Law No 5142-1 of the Russian Federation, on Donating Blood and Its Components, signed by B. Yeltsin, president of the Russian Federation, on 9 Jun 93]

[Text] This Law is called upon to regulate relations involved in development of donorship of blood and its components in the Russian Federation, implement an aggregate of social, economic, legal and medical steps to organize donorship and protect donor rights.

#### **Section 1. General Statutes**

##### **Article 1. Guidelines for donating blood and its components**

Donation of blood and its components is a freely expressed voluntary action.

Donations may be free or paid.

Only human blood and its components can be taken for therapeutic purposes.

Any competent citizen 18 to 60 years of age, who has undergone a physical examination may be a donor of blood and its components.

Taking blood and its components from a donor is permissible only if this would not cause harm to the donor.

##### **Article 2. Russian Federation Legislation on donating blood and its components**

Russian Federation legislation on donating blood and its components consists of this Law and legislative acts passed in accordance with it by the Russian Federation and republics of the Russian Federation.

The following are defined by Russian Federation legislation:

- basic guidelines for organizing donorship of blood and its components;

- rights and duties of donors in State health care institutions (further also referred to as health care institutions) within the said field;
- procedure for approving and funding the federal program of development of donorship of blood and its components;
- procedure for work, funding and material-technical support of health care institutions that procure, process, and store donor blood and its components;
- organization and procedure of quality control for blood, its components, preparations from donor blood and preservative solutions;
- procedure for negotiating international agreements with the Russian Federation dealing with matters of donating blood and its components, exchange of blood and its components, preparations from donor blood, as well as production of preparations derived from donor blood.

##### **Article 3. State programs of development of donorship of blood and its components**

The federal program of development of donorship of blood and its components is elaborated by the Council of Ministers—Russian Federation Government and approved by the Supreme Soviet of the Russian Federation. Monitoring its implementation is delegated to the Russian Federation Ministry of Health.

Republic (republics of the Russian Federation) and territorial (autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg) programs of development of donorship of blood and its components are elaborated by relevant State administrative agencies and approved by relevant supreme soviets and councils of people's deputies. Monitoring of implementation of these programs is delegated to health care agencies of republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

##### **Article 4. Funding of measures for development, organization and campaigning of donorship of blood and its components**

Measures dealing with development, organization and campaigning for donorship of blood and its components are implemented on the basis of federal, republic, territorial and local programs are funded by relevant budgets, as well as charitable contributions of Russian and foreign nongovernment and social organizations and citizens.

##### **Article 5. Duties of State administrative agencies and local self-government agencies in development, organization and campaigning of donorship of blood and its components**

Within the limits of their authority, State administrative agencies and local self-government agencies implement execution on their territories of State programs of development of donorship of blood and its components, funding and material-technical support of health care institutions that procure, process, and store donor blood



and its components, donor benefits established by legislation of the Russian Federation.

**Article 6. Duties of management of enterprises, institutions and organizations to assist in donorship of blood and its components**

Administrators of enterprises, institutions and organizations, regardless of forms of ownership, commanders (chiefs) of military units must:

- assist State and municipal health care institutions in enlisting donors;
- offer no obstruction to granting leave for workers who are donors to a health care institution on the day of examination and donation of blood and its components;
- provide the necessary space to take blood free of charge;
- provide benefits for workers who are donors, as established by legislation.

**Article 7. Involvement of social associations and organizations in campaigns among the public for donation of blood and its components**

The Russian Red Cross Society, other social associations, whose charter provides for assisting in public health, participate jointly with State health care administrative agencies in organizing donorship of blood and its components, its funding, as well as campaigning among the public for voluntary, free donations of blood and its components for therapeutic purposes.

**Section II. Donor Rights, Duties and Benefits**

**Article 8. State protection of donor rights**

The State guarantees to the donor the protection of his rights and health, and also provides benefits for him.

Officials of health care institutions must provide information about the duties of a donor and guarantees for safeguarding his health when donating blood and its components.

The donor is subject to mandatory insurance funded by the blood bank service as protection against transmission of communicable disease during performance of his donor functions. Cost of insurance should be included in cost of blood.

There is no charge for the physical examination of a donor prior to donating blood and its components, and for issuing information to him about his physical condition.

Following procedure established by Russian Federation legislation, a donor is compensated for damage caused to his health in connection with performance of his donor functions, including expenses for treatment, sociomedical expert evaluation, social-vocational and professional rehabilitation.

Disability of a donor occurring in connection with performance of his donor functions is equated to disability that occurs as a result of occupational injury.

**Article 9. Donor benefits**

A worker who is a donor is granted leave from work at an enterprise, institution or organization, regardless of forms of ownership, on the day he gives blood and its components, as well as on the day of his physical examination, with retention of his average earnings for these days. Military personnel who are donors, are relieved from details, guard duty and other forms of service.

In the event that, by agreement with management, a worker who is a donor comes to work on the day he donated blood (with the exception of work performed under special conditions), he is granted another day off, at his discretion, with preservation of mean earnings.

In the event that blood and its components are donated during annual leave, on a day off or holiday, another day off is granted at the donor's discretion, or else at least double pay is issued for the day of donating blood.

An additional day off, with preservation of mean earnings, is granted to the worker after each day of donating blood and its components. At the discretion of the donor, this day off can be added to annual leave or used at another time within a year of giving blood and its components.

Free food funded by the pertinent budget is provided to the donor on the day he gives blood.

**Article 10. Additional donor benefits**

A donor who has voluntarily given blood and/or its components free of charge in an amount totaling two maximum permissible units in the course of a year is granted the following additional benefits:—supplements equaling to 25 percent of scholarships for students at educational institutions for 6 months, funded by relevant budgets;—disability benefits for one year equaling the full wages, regardless of work tenure, for all types of diseases;—treatment for one year at State or municipal health care institutions funded by pertinent budgets;—priority issuance of travel passes on preferential terms for sanatorium and resort therapy according to place of work or education.

Republics of the Russian Federation, autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg have the right to set up other additional benefits for donors.

**Article 11. Benefits for individuals who have been awarded the "Honored Donor of Russia" badge**

Citizens who have been awarded the "Honored Donor of Russia" badge have to right to:



- treatment out of turn at State or municipal health care institutions;
- free manufacture and repair of dentures (with the exception of prosthesis made of precious metals) at State or municipal health care institutions;
- acquire drugs on preferential terms (with 50 percent discount) prescribed by State or municipal health care institutions;
- priority acquisition on preferential terms of travel passes for sanatorium and resort therapy according to place of work or education;
- annual paid leave at a convenient time;
- free travel in all forms of public transportation (with the exception of taxis);
- up to 50 percent discount for municipal services;
- preferential terms for individual housing construction.

Citizens of the Russian Federation who have been awarded the "Honored Donor of the USSR" badge enjoy all the benefits afforded to citizens awarded the "Honored Donor of Russia" badge.

#### **Article 12. Donor duties**

Citizens who have expressed their consent to be donors of blood and its components must give information known to them about prior and existing diseases, as well as use of narcotics.

A citizen who has deliberately concealed or distorted information about his physical condition is subject to liability as established by legislation of the Russian Federation, if such actions have or could lead to a substantial health disorder in recipients.

### **Section III. Organization of Donorship of Blood and Its Components**

#### **Article 13. Health care institutions that procure, process and store donor blood and its components**

Procurement, processing and storage of donor blood and its components are implemented by health care institutions (institutes, centers, stations, departments of blood transfusion) of the Russian Federation Ministry of Health, as well as pertinent health care institutions of other ministries and departments of the Russian Federation.

#### **Article 14. Procedure for taking blood and its components from a donor**

Blood and its components are taken after the donor has undergone a physical examination following procedure defined by the Russian Federation Ministry of Health.

#### **Article 15. Monitoring quality of donor blood and its components**

Blood, its components, preparations made from donor blood, and preservative solutions put out by institutions in the blood service are subject to mandatory monitoring by the Administration for Monitoring Quality of Drugs

and Medical Equipment, following procedure established by the Russian Federation Ministry of Health.

The procedure for interaction of institutions in the blood service and biological enterprises producing preparations from donor blood is defined by the Council of Ministers—Russian Federation Government.

#### **Article 16. Responsibility of officials in health care institutions**

Officials of health care institutions bear responsibility, in accordance with legislation of the Russian Federation, for violation of procedure for procurement, processing and storage of blood and its components, and use of preparations made from donor blood.

### **Section IV. Final Statutes**

#### **Article 17. Procedure for exchange of donor blood and its components, preparations from donor blood and their export from the Russian Federation**

The procedure for exchange of donor blood, its components, and preparations from donor blood with foreign medical organizations is established by the Russian Federation Ministry of Health.

Export of donor blood, its components and preparations from donor blood outside the Russian Federation is allowed in the case of rendering emergency humane aid in emergency situations by decision of the Council of Ministers—Russian Federation Government.

The sale of donor blood, its components and preparations made from donor blood to other nations for profit is prohibited.

#### **Article 18. Organization of donorship of blood and its components in emergency situations**

In cases of natural disasters, calamities, and accidents, epidemics, epizootics and other emergency circumstances over the entire territory of the Russian Federation or in some of its localities, donorship of blood and its components is organized following established procedure under the supervision of the Russian Federation Ministry of Health, republic, territorial and local health care administrative agencies.

Funding of all measures to organize donation of blood and its components, in the cases indicated in the first part of this Article is provided by the reserve funds of the Council of Ministers—Russian Federation Government, governments of republics of the Russian Federation, as well as reserve funds of autonomous oblasts, autonomous okrugs, krais, oblasts, cities of Moscow and St. Petersburg.

#### **Article 19. Effectiveness of international agreements**

If an international agreement of the Russian Federation stipulates rules other than those established by this Law, the rules of the international agreement apply.

**Decree to Put Into Effect the Russian Federation Law on Donating Blood and Its Components**

937C0395B Moscow ROSSIYSKAYA GAZETA  
in Russian 10 Jul 93 p 10

[Decree No 5142/1-1 of the Supreme Soviet of the Russian Federation to Put Into Effect the Russian Federation Law "On Donating Blood and Its Components", signed by R. I. Khasbulatov, chairman of the Supreme Soviet of the Russian Federation on 9 Jun 93]

[Text]The Supreme Council of the Russian Federation hereby decrees:

1. To put into effect the Russian Federation Law "On Donating Blood and Its Components" as of 1 September 1993.

2. The Council of Ministers—Russian Federation Government must do the following before 1 August 1993:

- bring decisions of the Council of Ministers
- Russian Federation Government into line with the said Law and implement revision and abolition by Russian Federation ministries and departments of enforceable enactments that contradict said Law;
- develop federal programs for: funding the work of State health care institutions that implement procurement, processing and storage of donor blood and its components; training medical and technical personnel in higher educational institutions, medical departments of universities, institutes for advanced training and medical schools to support work on procurement, processing and storage of donor blood and its components;
- define the list and organize activities of State health care institutions involved in procurement, processing and storage of donor blood and its components, with establishment of strict monitoring of performance of said health care institutions;
- reexamine the matter of establishing an assistance fund for donors of blood and its components.

3. The committee for public health and social security of the Supreme Soviet of the Russian Federation is to:—submit for consideration of the Supreme Soviet of the Russian Federation draft law on amendments to legislative acts of the Russian Federation related to adoption of said Law;—implement monitoring of implementation of this Decree.

**Kazakhstan Public Health Law**

937C0396A Almaty KAZAKHSTANSKAYA PRAVDA  
in Russian 22 Apr 93 p 2

[Law of Republic of Kazakhstan on amendment of the Kazakhstan Law "On Public Health Care in the Republic of Kazakhstan," signed by N. Nazarbayev, president of Kazakhstan Republic, on 31 Mar 93]

[Text]The Supreme Soviet of the Republic of Kazakhstan hereby decrees:

To make the following amendments in the Law of the Kazakhstan Republic "On Public Health Care in the Republic of Kazakhstan," dated 10 January 1992 (VEDOMOSTI VERKHOVNOGO SOVETA RESPUBLIKI KAZAKHSTANA, 1992, No [illegible], p 47):

1. Use the following wording for the first part of Article 23:

"A human being, human cadaver, as well as animals, can serve as donors of organ and tissue transplants."

2. Use the following wording for the third part of Article 23:

"The procedure for human-to-human, cadaver-to-human and animal-to-human organ and tissue transplantation is established by the Ministry of Health of the Republic of Kazakhstan."

**Decree on Law to Amend Kazakhstan Public Health-Care Law**

937C0396B Almaty KAZAKHSTANSKAYA PRAVDA  
in Russian 22 Apr 93 p 2

[Decree of the Kazakhstan Supreme Soviet to Put Into Effect the Kazakhstan Law on "Amendment of the Kazakhstan Law 'On Public Health Care in the Republic of Kazakhstan,'" signed by S. Abdildin, chairman of the Supreme Soviet of the Kazakhstan Republic, on 31 Mar 93]

[Text]The Supreme Soviet of the Republic of Kazakhstan hereby decrees:

1. To put into effect the Law of the Kazakhstan Republic "On Amendment of the Law of the Republic of Kazakhstan On Public Health Care in the Republic of Kazakhstan" as of the day of its publication.

2. The Cabinet of Ministers of the Republic of Kazakhstan is to implement the following before 1 July 1993:—bring decrees and orders of the government of the Republic of Kazakhstan into line with the said Law;—implement for revision and repeal by ministries and departments of their enforceable enactments, including instructions that contradict said Law.

**RF Decree on Pricing of Drugs and Medical Supplies**

937C0396C Moscow ROSSIYSKAYA GAZETA  
in Russian 31 Dec 92

[Decree No 970 of the Russian Federation Government, On Procedure for Setting Prices for Drugs and Medical Supplies, and Implementing Steps for Social Protection of the Public, dated 11 Dec 92, text furnished by Ye. Gaydar]

[Text] In order to improve supply of drugs and medical supplies, and to implement measures of social protection of the public, the Russian Federation Government hereby decrees:

1. To establish that essential and most important drugs, conforming to the list approved annually by the Russian Federation by agreement with the Russian Federation Ministry of Economics and Russian Federation Ministry of Finance, are to be sold to the public at a 50 percent discount off free prices when prescribed by physicians in medical-preventive [therapeutic and preventive care] institutions, enterprises, institutions and organizations of the pharmacy network, regardless of forms of ownership.

The Russian Federation Ministry of Health, in agreement with the Russian Federation Ministry of Economics and Russian Federation Ministry of Finance, is to approve, within 2 weeks, the list of essential and most important drugs sold to the public, when prescribed by physicians of medical-preventive institutions, at a 50-percent discount.

2. Approve the lists of population groups and disease categories in the outpatient treatment of which medically prescribed drugs and medical supplies are dispensed free of charge and with 50-percent discount off free prices, in accordance with appendixes No 1 and No 2.

The Russian Federation Ministry of Health, with participation of the Russian Federation Ministry of Finance and Russian Federation Ministry of Social Protection of the People, is to approve within a 3-week period procedure for dispensing drugs and medical supplies to the public and procedure for forwarding budgetary funds to cover expenses for this purpose.

3. Manufacturers are to sell drugs and medical supplies to all consumers at free prices.

Set a ceiling on profit level at 30 percent of the cost for enterprises (including enterprises of the pharmacy network), regardless of forms of ownership, which manufacture these types of products, for the purpose of precluding unwarranted rise of free prices for drugs and medical supplies.

4. Administrative agencies of Russian Federation republics, krais, oblasts and autonomous entities, cities of Moscow and St. Petersburg are to set a trade markup of no more than 50 percent of the free prices set by manufacturers for drugs and medical supplies, for enterprises, institutions and organizations of the pharmacy network, regardless of forms of ownership and number of intermediaries, and no more than 80 percent for regions of the Extreme North and areas equated with it.

5. To recommend that administrative agencies of republics in the Russian Federation, krais, oblasts, autonomous entities, cities of Moscow and St. Petersburg implement the following, within the limits of pertinent

budgets, in view of the increased cost of drugs and medical supplies:—raise the monetary expense norms for acquisition of drugs and medical supplies at hospitals, polyclinics, preschool institutions, homes for children, boarding schools, other health-care and social organizations in excess of the norms for monetary expenses adopted with approval of the Russian Federation budget for the same period;—provide additional preferential treatment in obtaining drugs and medical supplies for the population groups that are not listed in appendixes No 1 and No 2 attached to this decree, including large families and pregnant women;—provide financial support to State enterprises, institutions and organizations of the pharmacy network, the actual expenses of which exceed the maximum trade markups.

6. In order to expand output of drugs and medical supplies, allow all enterprises, regardless of forms of ownership, which dispose of the necessary conditions to manufacture such products, in accordance with established norms, with possession of special permit (license) from the Russian Federation Ministry of Health.

7. Allow enterprises, institutions and organizations of the pharmacy network, regardless of forms of ownership, to sell drugs and medical supplies only with a license issued by territorial health-care and pharmacy administrative agencies, by agreement with agencies of sanitary and epidemiological oversight.

8. The Russian Federation Ministry of Health, by agreement with the Russian Federation Ministry of Justice, is to approve within a 3-month period the procedure for issuing permits (licenses) for manufacture and sale of drugs and medical supplies.

9. The Russian Federation Ministry of Health and Russian Federation Ministry of Justice are to submit suggestions on amendments to existing legislation, in connection with adoption of this decree, within a 2-month period and following established procedure.

#### Appendix No 1

**List of population groups and disease categories, in the outpatient treatment of which medically prescribed drugs and medical supplies are dispensed free of charge, and list of drugs and medical supplies** Population groups

Participants in the Civil and Great Patriotic wars, combat operations in defense of the USSR among military personnel who served in military units, headquarters and institutions that were part of the active forces and former partisans; civilian personnel of the Soviet Army, Navy, troops and USSR internal affairs agencies holding regular jobs in military units, headquarters and institutions of the active forces during the Great Patriotic War or who participated in the defense of cities in which they were during that period, are credited for their years of service for purposes of granting pensions on preferential terms established for military units of the active forces. Invalids of the Great Patriotic War and those equated to them for benefits:



All drugs. Therapeutic mineral water (payment only for returnable container), medical leeches, telescopic glasses, patient care items (urinals, bedpans, therapeutic girdles of the Varitex, Zhibo and other types, magnetic applicators, brand ETNS-100-1 and ETNS-100-2 pain-relieving stimulators, elastic bandages and stockings. Surgical patients receive free dressing materials

All Drugs for: Parents and wives of servicemen who died of wounds, concussion or mutilation sustained in defense of the nation or in performing other military duties, or as a result of illness related to being on the front, citizens employed in Leningrad during the siege at enterprises, institutions and organizations of that city that were awarded the "For defense of Leningrad" medal, citizens awarded the "Resident of Leningrad under siege" badge

Former minor inmates of concentration camps. Ghettos and other places of detention set up by fascists and their allies during World War II. Former military internationalists who participated in combat operations in the Republic of Afghanistan and on the territory of other countries: Children up to the age of 3 years, as well as children of large families up to the age of 6 years. Group I invalids, unemployed group II invalids, disabled children up to 16 years old.

All drugs, medical rehabilitation equipment, bedpans, urinals and dressing materials for:

Individuals exposed to radiation as a result of the Chernobyl disaster, including: a) individuals who acquired or suffered from radiation sickness as a result of the Chernobyl disaster, or involved in work to eradicate the sequelae of the disaster at the Chernobyl AES [Nuclear Power Plant].

All drugs, free fabrication and repair of dental prostheses (with the exception of those made of precious metals)

b) those disabled as a result of the Chernobyl accident, including: individuals (including those sent there on temporary or official assignment) who participated in eradication of sequelae of the disaster within the condemned zone or engaged in operation or other work at the the Chernobyl AES; military personnel and reservists called to special muster and involved in work related to eradication of sequelae of the Chernobyl disaster, regardless of site of relocation and work performed, as well as executive and rank-and-file personnel of internal affairs agencies who served (are serving) in the condemned zone; individuals evacuated from the condemned zone and resettled from the relocation zone, or who left voluntarily from these zones; individuals who donated bone marrow to save lives of victims who were affected by the Chernobyl disaster, regardless of time elapsed between the bone marrow transplant and onset of disability related to it.

All drugs, free fabrication and repair of dental prostheses (with the exception of those made of precious metals)

c) individuals (including those on temporary or official assignment) who participated in 1986-1987 in eradicating the sequelae of the Chernobyl disaster within the condemned zone or work related to evacuation of the public, material assets, livestock, and operation of or other work at the Chernobyl AES; military personnel and reservists called to special muster in this period to perform work related to eradication of the sequelae of the Chernobyl disaster, including airlifts; technical-engineering personnel in the civil aviation, regardless of site of relocation and job performed; executives and rank-and-file personnel of internal affairs agencies who served in the condemned zone in 1986-1987; military personnel and reservists called to muster and involved in work on the "Shelter" project in 1988-1990, as well as junior and midlevel medical personnel, physicians and other employees of medical institutions (with the exception of those whose professional activities involve work with all forms of sources of ionizing radiation in a workplace exposed to radiation consistent with their special field of work), who were exposed to above-norm doses of radiation while rendering medical care and services, in the period from 26 April to 30 June 1986, to victims of the Chernobyl disaster who were a source of ionizing radiation.

All drugs, free fabrication and repair of dental prostheses (with the exception of those made of precious metals)

d) blue- and white-collar workers, as well as military personal, executive and rank-and-file personnel of internal affairs agencies who acquired occupational diseases related to radiation exposure while working in the condemned zone.

All drugs, free fabrication and repair of dental prostheses (with the exception of those made of precious metals)

e) individuals evacuated (including those who left voluntarily) from the condemned zone in 1986, and children, as well as infants who were at the stage of intrauterine development at the time of evacuation.

All drugs, free fabrication and repair of dental prostheses (with the exception of those made of precious metals)

f) children and adolescents up to 18 years old who live in the relocation zone and residence zone with the right to relocation, who were evacuated and resettled from the condemned, relocation zones, and residence zone with right to relocation, including those at the stage of intrauterine development on the day of evacuation, as well as children of the first and subsequent generations, those listed in items a), b), c) and d) who were born after exposure of one of their parents to radioactive radiation as a result of the Chernobyl disaster:

All drugs, preventive agents, dressing materials

g) children and adolescents residing in the zone of preferential socioeconomic status:

All drugs, preventive agents and dressing materials



h) children and adolescents with diseases resulting from the Chernobyl disaster or attributed to genetic sequelae of exposure of their parents to radioactive radiation, as well as children of subsequent generations who developed diseases resulting from the Chernobyl disaster or attributed to genetic sequelae of exposure of their parents to radioactive radiation:

All drugs, free fabrication and repair of dental prosthesis (with the exception of prostheses made of precious metals)

i) individuals who live (work) on territory of residence zone with right to relocation:

All drugs

j) individuals who live (work) in territory of residence zone with preferential socioeconomic status:

All drugs.

k) individuals who lived (worked) in the relocation zone prior to resettlement to other regions:

All drugs.

l) military and civilian personnel in the USSR Armed Forces, troops and agencies of the USSR Committee for State Security, interior troops, railroad troops and other military units classified as citizens of special risk subdivisions ["podrazdeleniya"]; those directly involved in atmospheric testing of nuclear weapons, military radioactive substances and training involving use of such weapons prior to the date of actual cessation of such tests and training; direct participants in underground nuclear arms tests in irregular radiation situations and exposed to other deleterious factors of nuclear arms; direct participants in eradication of radiation accidents at nuclear installations of above-water and underwater vessels and other military objects; military personnel of different subdivisions involved in assembly of nuclear warheads; immediate participants in underground nuclear arms testing, performance and implementation of work on collection and burial of radioactive substances:

All drugs, free fabrication and repair of dental prostheses (with the exception of prostheses made of precious metals)

Individuals who have or have had radiation sickness or who became disabled as a result of radiation accidents and their sequelae at other (than the Chernobyl AES) civilian or military nuclear installations, as a result of testing, training and other work related to all types of nuclear installations, including nuclear arms and space technology: All drugs, free fabrication and repair of dental prostheses (with the exception of prostheses made of precious metals).

Small ethnic populations of the North in Chukotsk, Koryaki, Yamal-Nenetskiy, Khanty-Mansiysk autonomous okrugs, Severo-Evenskiy, Srednekanskiy and Ol'skiy rayons of Magadan Oblast:

All drugs

#### Categories of diseases

Childhood cerebral paralysis:

Drugs for treatment of this category of diseases

Hepatocerebral dystrophy and phenylketonuria:

Protein-free food, protein hydrolysates, enzymes, psychostimulants, vitamins, biostimulants

Cystic fibrosis (in children).

Enzymes

Acute intermittent porphyria:

Analgesics, beta-blockers, phosphadene, riboxin, androgens, adeny

AIDS, HIV infection:

All drugs

Oncological diseases:

All drugs, dressing materials for incurable oncological patients

Hematological diseases, hemoblastosis, cytopenia, hereditary hemopathies: Cytostatics, immunosuppressants, immunocorrective agents, steroid and nonsteroid hormones, antibiotics and other agents for treatment of such diseases and correction of complications of therapy

Radiation sickness:

Drugs needed to treat this disease

Leprosy:

All drugs.

Tuberculosis:

Antituberculosis agents, liver-protective agents.

Severe brucellosis:

Antibiotics, analgesics, nonsteroid and steroid anti-inflammatory agents

Chronic, severe, systemic skin diseases:

All drugs for treatment of these diseases.

Bronchial asthma:

Drugs prescribed for this disease.

Rheumatism and rheumatoid arthritis, systemic (acute) lupus erythematosus, spondylitis deformans:

Steroid hormones, cytostatics, colloid gold preparations, anti-inflammatory nonsteroid agents, antibiotics, antihistamines, cardiac glycosides, coronarolytics, diuretics, Ca antagonists, K preparations, chondroprotective agents.

Myocardial infarction (first 6 months):

Drugs needed to treat this disease.

Postoperative condition after heart valve replacement:

Anticoagulants.

Organ and tissue transplants:

Immunosuppressants, cytostatics, steroid hormones, antifungal, antiherpetic and anti-immunoviral agents, antibiotics, uroseptics, anticoagulants, disaggregants, coronarolytics, Ca antagonists, K preparations, hypotensive, spasmolytic, diuretic, liver-protective agents, pancreatic enzymes.

Diabetes:

All drugs.

Pituitary dwarfism:

Anabolic steroids, somatotrophic hormone, sex hormones, insulin.

Premature sexual development:

steroid hormones, parlodel, androcur.

Multiple sclerosis:

Drugs needed for treatment of this disease.

Myasthenia:

Anticholinesterase drugs, steroid hormones.

Myopathy:

Drugs needed for treatment of this disease.

Marie's cerebellar ataxia:

Drugs needed for treatment of this disease.

Parkinson's disease:

Anti-parkinsonism drugs.

Chronic urological diseases:

Pezzer catheters.

Syphilis:

Antibiotics, bismuth preparations.

Glaucoma, cataract:

Anticholinesterase, cholinomimetic, dehydrating, diuretic agents.

Mental illness (groups I and II disability, as well as patients employed in occupational therapy workshops of psychiatric and neuropsychiatric institutions): All drugs.

## Appendix No 2

List of population groups under outpatient treatment of whom drugs, which do not appear on the list of essential and most important drugs, are dispensed when prescribed by physicians of medical-preventive institutions at a 50 percent discount off free prices.

Pensioners who receive minimal old-age, disability pensions, or pensions because of loss of breadwinner.

Employed Group II invalids, Group III invalids\*), when they are declared to be unemployed according to established procedure.

Individuals (including those on temporary or official assignment) who participated in 1988-1990 in work to eradicate sequelae of the Chernobyl disaster within the condemned zone or engaged in this period in operation of or other work at the Chernobyl AES; military personnel and reservists called up for special muster and participation during these years in work related to eradication of the sequelae of the Chernobyl disaster, regardless of place of relocation and work performed, as well as executive and rank-and-file personnel of internal affairs agencies who served in the condemned zone in 1988-1990.

Individuals who suffered repressions in the form of incarceration, exile or deportation, who have been rehabilitated in accordance with the RSFSR Law "On rehabilitation of victims of political repressions" (as well as individuals committed without justification in psychiatric institutions on political grounds, who have a disability or are pensioners).

\*Invalids with Group III disability also have the right to acquire medical supplies at a 50-percent discount, when declared to be unemployed according to established procedure.

## RF Law on Licensing of Pharmaceutical Industry 937C0398A ROSSIYSKIYE VESTI in Russian No 33, 17 Feb 93 p 6

[Instructions On Procedure for Licensing Pharmaceutical Activities of Pharmacy Institutions and Pharmacy Enterprises in the Russian Federation, approved by A. Ye. Vilken, deputy health minister of the Russian Federation]

[Text]

### 1. General statutes

1.1. Licensing of pharmacy institutions and pharmacy enterprises (referred to hereafter as pharmacy institutions) is a means of State monitoring of adherence of

pharmacy institutions to legislative requirements pertaining to their legal-organizational status, pharmaceutical activities related to dispensing drugs to the public.

1.2. The work of a pharmacy institution, regardless of legal-organizational form or form of ownership, is prohibited without a State license. If this statute is violated, there is liability in the form of prohibition of pharmaceutical activity.

1.3. In accordance with the Russian Federation Law "On Public Health Insurance in the RSFSR," licensing of pharmacy institutions is implemented by licensing commissions created by State administrative agencies on the federal level (for the Russian Federation), in republics, autonomous entities, cities of Moscow and St. Petersburg.

1.4. Licensing of pharmacy institutions is carried out in strict accordance with existing legislation, these instructions, standards and methodological documentation approved by State administrative agencies and the Russian Federation Ministry of Health, which regulate the activities of pharmacy institutions and requirements as to quality of drugs dispensed to the public.

1.5. The State license for the right to engage in pharmaceutical activities must contain the following:—full name of pharmacy institution with indication of its legal-organizational form;—location of the pharmacy institution;—permission for pharmaceutical activity in the system of dispensing drugs to the public;—license number;—date of registration of license.

1.6. All types of pharmaceutical activities, including those listed below, carried out by pharmacy institutions are subject to licensing:—compounding of all types of drugs prescribed by physicians or requested by medical-preventive [medical and preventive care] institutions;—compounding of all types of refillable drugs prescribed by physicians in small series;—monitoring technology of compounding, storage, quality of ready-made drugs and medication that are compounded in pharmacies, medicinal plant raw material and preparations of the latter;—procurement, storage, organization, delivery, dispensing drugs and medical supplies to pharmacies and medical-preventive institutions;—selling drugs, both those compounded in pharmacies and ready-made, and medical supplies permitted for use in the Russian Federation to the public and medical-preventive institutions.

1.7. Licensing of pharmacy institutions is carried out when new pharmacy institutions are opened, when pharmacy institutions change their legal-organizational form and forms of ownership, upon expiration of a previously issued license.

1.8. Licensing may be carried out in advance at the initiative of a pharmacy institution in order to receive a license for new types of drugs and services, at the initiative of State executive agencies, in the event of revocation or suspension of a license, by court order.

## **2. Procedure for pharmacy institutions to obtain a license**

2.1. In order to obtain a State license, the pharmacy institution submits the following documentation to the licensing commission:

2.1.1. Application;

2.1.2. Copy of certificate (notarized) of State registration of institution (enterprise);

2.1.3. Copies (two) (notarized) of applicant institution's Charter or Statute, following established procedure;

2.1.4. Copy (notarized) of order or lease of premises and equipment;

2.1.5. Types of pharmaceutical activities, services for which application for a license is submitted;

2.1.6. Finding of State sanitary inspectorate;

2.1.7. Finding of State fire-safety inspectorate;

2.1.8. Finding on operating condition of building (premises);

2.1.9. Accreditation certificates of pharmacy institutions and personnel;

2.1.10. Copy of prior license (for institutions licensed previously). 2.1.11. Copy of payment authorization in payment of the one-time charge for the license.

2.2. Licensing procedure is determined by the commission and consists of examination of documentation submitted by the pharmacy institution, forming an expert on-site opinion and issuing a license.

2.3. Documentation is examined within time limits set by a State administrative agency.

If the documentation submitted by a pharmacy institution does not conform to the requirements, it is returned to the applicant within time limits set by the State administrative agency. The record contains detailed information on all types of pharmaceutical activities that have undergone licensing.

2.4. After undergoing the licensing process according to established procedure, the pharmacy institution receives a license and license record (appendixes 1 and 2) giving the right to engage in pharmaceutical activities in the declared scope (with restrictions), or else a validated denial of a license. The record indicates in detail all the types of pharmaceutical activities that have been licensed.

2.5. Expiration date of a license is set by the State administrative agency.

2.6. License forms and licensing records are strictly accountable documents, they are produced in printed form, with designation of series and number.

2.7. Revocation or suspension of a license to engage in pharmaceutical activities is implemented by the licensing commission upon request of the accreditation commission, and the pharmacy institution is so informed in writing.

2.8. A license to engage in pharmaceutical activities can be suspended and revoked in the following cases:—violation by the pharmacy institution of existing legislation, standards and methodological documentation approved by the Russian Federation Ministry of Health, which defines the procedure for operation of pharmacy institutions and requirements as to quality of dispensing drugs to the public, and standards of pharmacy institutions;—change in Charter and types of activities in a pharmacy institution without reregistering with the licensing commission.

2.9. Prior to receiving a license, a pharmacy institution and physical entities that carry out individual or collective activities in the drug-dispensing system must undergo accreditation in accordance with procedure effective in the Russian Federation.

2.10. The pharmacy institution pays a one-time charge for the license in the amount established by the territorial State administrative agency.

2.11. Documentation related to licensing must be kept on file for at least 10 years. After this term, said documentation is transmitted to archives.

### 3. Rights and duties of licensed pharmacy institutions

3.1. The pharmacy institution to be licensed has the right to:—appeal the decision of territorial licensing commissions;—undergo early licensing in the cases stipulated in item 1.8 of these instructions;—invite independent experts to attend the licensing procedure, to be coordinated with the licensing commission.

3.2. The pharmacy institution to be licensed is obliged to:—submit an application and necessary documentation for licensing within the prescribed time limit;—submit reliable information in documentation submitted to the licensing commission;—remit the charge for issuing the license;—provide representation of the pharmacy institution (enterprise) at meetings of the licensing commission.

### 4. Procedure for resolving disputes and liability of the parties

4.1. In the event of disagreement with refusal to issue a license, revoke or suspend it, the pharmacy institution has the right to turn to the republic-level licensing commission.

#### Appendix 1 or Instructions on Procedure for Licensing Pharmaceutical Activities of Pharmacy Institutions and Pharmacy Enterprises in the Russian Federation Russian Federation

(name of territorial commission) License

Registration number

(name and description of institution)

Entered in territorial register on 20 19

The pharmacy institution (enterprise) is permitted to work in the system of drug support of the public in accordance with the attached record.

Chairman of the licensing commission 20 (signature)  
Place for seal

#### Appendix 2 for Instructions on Procedure for Licensing Pharmaceutical Activities of Pharmacy Institutions and Pharmacy Enterprises in the Russian Federation

#### Record of License No dated 20 19

In accordance with the decision of the licensing commission dated 20 19 the institution 70 (full name of institution) is permitted to carry out the following forms of pharmaceutical activities and services:

1. Dispensing drugs to the public and medical-preventive institutions.

Signature of chairman of licensing commission

Place for seal

#### Decree on Hygienic Certification of Products

937C0398B Moscow ROSSIYSKIYE VESTI in Russian  
No 26, 9 Feb 93 p 5

[Decree No 1 of RSFSR State Committee for Sanitary and Epidemiological Oversight On Procedure for Issuing Hygienic Certificates for Products, signed by Ye. N. Belyayev, chairman of the Russian Goskomsanepidnadzor on 5 Jan 91, Moscow]

[Text]For the purpose of preventing adverse effects on human health of factors related to production and use in the national economy and by consumers of products that are potentially hazardous to human health, and in execution of the RSFSR Law "On Sanitary and Epidemiological Welfare of the Public," the Russian Goskomsanepidnadzor [State Committee for Sanitary and Epidemiological Oversight]

hereby decrees:

1. To adopt the hygienic certificate, as form of coordinating the production, introduction and use of products that are potentially hazardous to human health.

2. To establish that hygienic certification of products, standards documentation for which was previously coordinated by Goskomsanepidnadzor, is to be implemented when such documentation is reviewed.

3. To approve the attached Statute on the procedure for issuing hygienic certificates for products; types of products for which hygienic certificates are needed and form of hygienic certificate.



4. Agencies and institutions of the Russian State Sanitary and Epidemiological Service must issue hygienic certificates for products in accordance with requirements of sanitary legislation of the Russian Federation and the Statute adopted by this decree.

5. In the first 6 months of 1993, enterprises, organizations and institutions, regardless of departmental affiliation and forms of ownership, as well as other juridical and physical entities involved in production and sale of potentially hazardous products, must write up standards documentation that has not been previously coordinated following established procedure.

6. Appendixes 1 and 2 of Decree No 4 of the RSFSR Goskomsanepidnadzor dated 24 April 1992 are deemed to be ineffective.

#### **Statute on Procedure for Issuing Hygienic Certificates for Products**

1. The hygienic certificate constitutes permission to agencies and institutions of the State Sanitary and Epidemiological Service to produce (import) products that conform to established requirements, and it serves as the official confirmation of product safety to human health under specific conditions.

2. Hygienic certificates are mandatory for products that could have an adverse effect on human health during manufacture, storage, transportation, application and use.

3. Hygienic certificates are issued by agencies and institutions of the State sanitary and epidemiological Service of the Russian Federation at the stage of coordination of standards documentation and delivery of products to industry or of writing up contracts (agreements) when purchasing new foreign products.

4. There are requirements of sanitary legislation in effect on the territory of the Russian Federation for issuing hygienic certificates for imported products, unless otherwise stipulated by international contracts (agreements).

5. Hygienic certificates are issued for:—domestic products, on the basis of findings of hygienic evaluation of products and expert evaluation of standards documentation which defines the specifications for products, their manufacture and application;—imported products, on the basis of evaluation of supplier country's certificate of safety issued by an authorized agency and/or findings of product testing carried out in Russia.

6. Hygienic evaluation of products.

6.1. Hygienic evaluation of products refers to determination of their possible adverse effect on human health, establishment of permissible areas and conditions of product use, as well as formation of requirements as to manufacturing processes, storage, transportation, operation (application) and use of products that would assure their safety to man.

6.2. Hygienic evaluation of products is carried out by institutions of the State Sanitary and Epidemiological Service on the basis of results of its own contractual testing or on the basis of evaluating results of tests carried out by other organizations accredited for this purpose.

6.3. It is the duty of the developer (manufacturer, seller) of a product to organize studies of hygienically significant parameters and features of the product, and to elaborate the necessary safety measures.

6.4. Institutions and laboratories that test hygienically significant product parameters and characteristics must be governed by the methods approved by the Russian Goskomsanepidnadzor, or by methods approved by the USSR Ministry of Health in effect on the territory of the Russian Federation.

7. Hygienic certificates are prepared according to established form.

A hygienic certificate may be issued for a limited time and limited volume of product manufacture (import).

8. Hygienic certificates for products are issued by:—the Russian Goskomsanepidnadzor for baby food, pesticides, food supplements, new (nontraditional) forms of raw materials, as well as products purchased by international agreements;—republic (republics of the Russian Federation), kray, oblast, cities of Moscow and St. Petersburg sanitary and epidemiological oversight centers for all other types of products.\*

9. The time limit for examining material when issuing a hygienic certificate is 1 month; when material is referred for expert evaluation in specialized organizations, this term can be extended to 2 months (applicant must be informed about the change in time limit for an answer).

10. The hygienic certificate is valid over the entire territory of the Russian Federation unless otherwise stipulated.

11. In case of disagreement of the applicant with the decision of the territorial Goskomsanepidnadzor center not to issue a hygienic certificate, this decision may be appealed to the Russian Federation Goskomsanepidnadzor.

\*for machine-building and instrument-making products, at the site of acceptance tests; for other products, at the site of the developer organization.

[Signed:] V. I. Chiburayev, Chief of Goskomsanepidnadzor Administration Approved by Decree No 1 of the Russian Goskomsanepidnadzor dated 5 Jan 93

#### **Description of institution**

##### **Hygienic Certificate**

(full name of product) date 20 No 10 1. 70) (standards documentation for domestic products, description of imported products) is consistent with Russian sanitary

legislation and conforms to it 2. 60 20 (name of product) conforms to 50 10 (standards documentation, delivery documentation) according to hygienic parameters, permission granted to manufacture (import) products for sale on the territory of the Russian Federation for use as: 70 under the following conditions: 70 3. Hygienic description of product 20 parameters 30 permissible levels 20 (factors) 33 (values) 3.1. 3.2. 3.3. 4. In use (storage, transportation, sale) of 46 (name of product) the following safety measures must be applied 5. This certificate is valid for 35 (term, batch size)

Chief State health inspector [physician] 20 on behalf of 5 (territory) 20 surname, name and patronymic 50 [date] 10 199

Approved, Decree No 1, Russian Goskomsanepidnadzor, dated 5 Jan 93

#### Types of products that need a hygienic certificate

1. Raw materials for foodstuffs, foods, food supplements, preservatives; materials and items made with them that come in contact with foodstuffs.
2. Merchandise for children: games and toys, clothing (including bed linen), shoes, books and educational aids, furniture, baby carriages, bookbags; artificial, polymer and synthetic fabrics, substances for manufacture of children's merchandise.
3. Materials, equipment and substances used in the system of water supply, including potable water.
4. Perfumes and cosmetics.
5. Chemical and petrochemical products for industrial purposes, consumer chemicals, chemical agents used in agriculture, including mineral fertilizers.
6. Polymer and synthetic materials for use in construction, transportation, as well as building furniture and other household items; chemical fibers and thread; textile, sewing and knit materials containing chemical fibers and ancillary textile substances; artificial and synthetic leather and textiles for shoes.
7. Machine-building and instrument-making products for industrial and consumer use.
8. Products that come in contact with human skin.

#### Decree on Ensuring Product Safety

937C0409A Moscow ROSSIYSKIYE VESTI in Russian 9 Feb 93 p 3

[ of Products to Human Health, signed by S. F. Bezverkhiy, chairman of Russian Gosstandart and Ye. N. Belyayev, chairman of Russian Goskomsanepidnadzor on 5 Jan 93]

[Text] State Committee of the Russian Federation for Standardization, Metrology and Certification [Gosstandart], State Committee for Sanitary and Epidemiological Oversight [Goskomsanepidnadzor] of the Russian Federation

#### Decree

For the purpose of prevention of deleterious effects on human health of factors related to production and use in the national economy and by consumers of products that are potentially hazardous to human health, and in execution of the RSFSR Law "On Sanitary and Epidemiological Welfare of the Public" and Russian Federation Law "On Protection of Consumer Rights," the Russian Goskomsanepidnadzor and Russian Gosstandart hereby decree:

1. To establish that the mandatory certification of safety of products, to which the hygienic requirements stipulated by the Russian Goskomsanepidnadzor apply, is carried out in the presence of a hygienic certificate, which is issued by Russian Goskomsanepidnadzor agencies following procedure established by this committee
2. Accreditation of certification agencies and testing centers (laboratories) for the right to certify and test for safety and harmlessness to human health is carried out jointly by Russian Gosstandart and Goskomsanepidnadzor agencies authorized to perform this work following procedure established by instruments of the Certification System, GOST R.
3. To delegate to the Russian republic information-analysis center of the Russian Goskomsanepidnadzor (to L. G. Podunov) the duties of the organizational and methodological center of the Russian Goskomsanepidnadzor dealing with participation of the State sanitary and epidemiological service in joint work with the Russian Gosstandart for accreditation of organizations that carry out certification of merchandise (work, services), as well as testing laboratories (centers) for carrying out certification tests.

#### Procedure for Referring Citizens of the Russian Federation for Treatment and Sending Medical Specialists on Assignment Abroad and Receiving Foreigners for Treatment in the Russian Federation

937C0411A Moscow VRACH in Russian No 1, Jan 93 pp 4-6

[Order No 218 of the Russian Federation Ministry of Health dated 3 Aug 1992, signed by Minister A. I. Vorobyev]

[Text] In order to regularize work dealing with organization of referrals of Russian Federation citizens for treatment abroad, receiving foreigners for treatment in the Russian Federation, sending specialists abroad on assignment, and receiving foreign specialists to administer medical care,

**Approval is hereby given for:**

1. The members of commissions of the Russian Federation Ministry of Health to deal with screening of patients (adults and children) for referral for treatment abroad.
2. The list of research institutes and departments of medical institutes that provide conclusions as to desirability of referring a patient for treatment abroad (Appendix 3).

**It is hereby ordered that:**

1. Administrators of territorial health care administrative agencies must:

1.1. Inform medical-preventive [therapy and preventive care] institutions and concerned parties that the ruble equivalent in foreign currency allocated for treatment abroad will be deposited by citizens or their sponsors according to a special exchange rate for noncommercial operations at the expense of the republic hard currency reserve of the Russian Federation.

1.2. Forward a petition to the Medical Care Administration and Administration for Mother and Child Health Care, of the Russian Federation Ministry of Health, with enclosure of:—conclusion of chief research institute in the pertinent specialty as to desirability of referring the patient abroad for treatment;—written guarantee for coverage in rubles for the foreign currency needed to treat the patient and for the stay abroad of his companion;—detailed excerpt from the case history, typed in 2 copies, in English, containing all necessary information about the patient's condition, examination and treatment administered;

2. Directors of research institutes and heads of medical institutes (Appendix 3) when instructed by health care agencies and institutions must:

2.1. Proceed, in making decisions on the desirability of referral for treatment abroad, from the fact that to be referred abroad, citizens must have been submitted to all therapeutic methods permitted in the Russian Federation for use at medical-preventive institutions of the republic, and that additional or new methods, that are not used in the Russian Federation, could be used on them abroad.

2.2. Address well-reasoned, personally signed conclusions to requesting health care agencies and institutions, and in the case of a positive decision, include information about the reasons for desirability of referring a patient and his companion abroad, the country (countries) and medical centers where needed care can be administered, and approximate cost of treatment.

3. Consider the following to be no longer in force: Instructions No 83/21-03 of the RSFSR Ministry of Health "On procedure for referral of Soviet citizens for treatment, sending medical specialists abroad and receiving foreigners for treatment in the USSR," dated

13 Feb 90; Instructions No 43-u of the Russian Federation Ministry of Health "On creation of a commission for screening children for treatment abroad," dated 5 Mar 92; Instructions No 92-u of the Russian Federation Ministry of Health "On regularizing work dealing with referral of Russian Federation citizens for treatment abroad," dated 24 Apr 92.

In connection with the foregoing, N. N. Vaganov and A. M. Moskvichev, deputy health ministers of the Russian Federation, should annul the agreement with the "Sovmed Plus" International Medical Consultation Center.

4. Reprinting of this order in the required number of copies and delivery thereof to all concerned health care agencies and institutions are permitted.

5. N. N. Vaganov and A. M. Moskvichev, deputy health ministers of the Russian Federation, are entrusted to monitor implementation of this order.

**Appendix 3 to Order No 218 of the Russian Federation Ministry of Health dated 3 August 1992**

[Signed by:] O. V. Rutkovskiy, chief of Medical Care Administration, and D. I. Zelinskaya, Chief of Administration for Mother and Child Health Care

**List of Research Institutes and Departments of Medical Institutes That Make Conclusions on Desirability of Referring Patients for Treatment Abroad**

1. **Transplantology**—NII [scientific research institute] of Transplantology and Artificial Organs, Russian Federation Ministry of Health (director: Academician V. I. Shumakov)

2. **Proctology**—NII of Proctology, Russian Federation Ministry of Health (director: Professor G. I. Vorobyev)

3. **Urology, hemodialysis, andrology**—NII of Urology, Russian Federation Ministry of Health (director: Academician N. A. Lopatkin)

4. **Cardiology**—Cardiological Research Center of the Russian AMN [Academy of Medical Sciences] (director: Academician Ye. I. Chazov)—Therapy department, Russian State Medical University (department head: Professor V. A. Lyusov, chief cardiologist of the Russian Federation Ministry of Health)

5. **Pulmonology**—Moscow NII of Pulmonology, Russian Federation Ministry of Health (director: Academician A. G. Chuchalin)

6. **Rheumatology**—Institute of Rheumatology, Russian AMN (director: Academician V. A. Nasonova)—Department of Therapy, Russian State Medical University (department head: Professor V. N. Anokhin, chief rheumatologist of the Russian Federation Ministry of Health)

7. **Endocrinology**—Endocrinological Research Center, Russian AMN (director: I. I. Dedov, corresponding



member of the Russian AMN)—Department of Endocrinology, Moscow Medical Stomatological Institute imeni N. A. Semashko (department head: Professor M. I. Balabolkin) (diabetes mellitus)

**8. Gastroenterology**—Central NII of Gastroenterology, Main Medical Administration of Department of Social and Cultural Sectors of the Government of Moscow (director: Academician A. S. Loginov)

**9. Phthisiology**—Central NII of Tuberculosis, Russian AMN (director: Academician A. G. Khomenko)

**10. Dermatovenereology**—Central Dermatological and Venereological Institute, Russian Federation Ministry of Health (director: Academician Yu. K. Skripkin)

**11. Infectious diseases**—Department of Infectious Diseases, Moscow Medical Stomatological Institute imeni N. A. Semashko (department head: Professor N. D. Yushchuk)

**12. Immunology, allergology**—Institute of Immunology, Russian AMN (director: Academician R. M. Khaitov)

**13. Ophthalmology**—Moscow NII of Eye Diseases imeni Gelmgolts, Russian Federation Ministry of Health (director: Professor A. M. Yuzhakov)

**14. Otorhinolaryngology**—Moscow NII for Ear, Nose and Throat, Russian Federation Ministry of Health (director: Professor D. I. Tarasov)

**15. Neurology**—Institute of Neurology, Russian AMN (director: Academician A. V. Vereshchagin)—Department of Neurology and Neurosurgery, Russian State Medical University (department head: Professor Ye. I. Gusev, corresponding member of Russian AMN)

**16. Neurosurgery**—NII of Neurosurgery imeni N. N. Burdenko, Russian AMN (director: Academician A. N. Kononov)—St. Petersburg Research Institute of Neurosurgery imeni A. L. Polenov, Russian Federation Ministry of Health (director: Professor V. P. Berstnev)

**17. Traumatology, orthopedics**—Central Institute of Traumatology and Orthopedics imeni N. N. Priorov, Russian Federation Ministry of Health (director: Professor Yu. G. Shaposhnikov)—St. Petersburg NII of Traumatology and Orthopedics imeni R. R. Vreden, Russian Federation Ministry of Health (director: Professor N. V. Kornilov, chief traumatologist of the Russian Federation Ministry of Health)—Department of Traumatology, orthopedics and Military Field Surgery, Moscow Medical Stomatological Institute imeni N. A. Semashko (department head: Professor A. S. Imamaliyev, corresponding member of the Russian AMN, chief orthopedist of the Russian Federation Ministry of Health)

**18. Cardiovascular surgery**—Institute of Cardiovascular Surgery imeni A. N. Bakulev, Russian AMN (director: Academician V. I. Burakovskiy)—Surgical Research Center, Russian AMN, Center for Critical Arterial

Pathology (administrator: Professor Yu. V. Belov)—Institute of Surgery imeni A. V. Vishnevskiy, Russian AMN, scientific methodological center for arterial pathology (administrator: A. V. Pokrovskiy, corresponding member of the Russian AMN)—Department of Faculty Surgery, Russian State Medical University, republic scientific-methodological center for phlebology (administrator: Academician V. S. Savelyev)

**19. Microsurgery**—Surgical Research Center, Russian AMN (administrator: B. A. Konstantinov, corresponding member of the Russian AMN)

**20. Hematology**—Hematological Research Center, Russian Federation Ministry of Health (administrator: Academician A. I. Vorobyev)—St. Petersburg NII of Hematology and Blood Transfusion, Russian Federation Ministry of Health (director: Docent Ye. A. Selivanov)

**21. Oncology**—Oncological Research Center, Russian AMN (administrator: Academician N. N. Trapeznikov)—Moscow Oncological Research Institute imeni P. A. Gertsen, Russian Federation Ministry of Health (director: Professor V. I. Chissoy)

**22. Stomatology**—Moscow Medical Stomatological Institute imeni N. A. Semashko (head: Professor Ye. I. Sokolov, corresponding member of the Russian AMN)

**23. Gynecology**—Moscow Oblast NII of Obstetrics and Gynecology (director: Professor V. I. Krasnopolskiy)—Department of Obstetrics and Gynecology, Therapeutic Division of Moscow Medical Stomatological Institute imeni N. A. Semashko (department head: O. N. Serov, corresponding member of the Russian AMN)

**24. Children's neurological diseases**—Department of Pediatric Neurology, Russian State Medical University (department head: L. O. Badalyan, academician of the Russian AMN)—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)

**25. ENT diseases in children**—Moscow NII of the Ear, Nose and Throat, Russian Federation Ministry of Health (director: Professor D. I. Tarasov)—Department of Otolaryngology, pediatrics division, Russian State Medical University (department head: Professor M. A. Bogomelskiy)

**26. Childhood pulmonology**—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)

**27. Childhood uronephrology**—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)—Department of Child Surgery, Russian State Medical University (department head: Professor Yu. F. Isakov, academician of the Russian AMN)

**28. Childhood gastroenterology**—Department of Propaedeutics of Childhood Diseases, Russian State Medical University (department head: Professor V. A. Filin)



**29. Childhood allergology**—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)

**30. Childhood hereditary diseases**—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)

**31. Childhood skin diseases**—Sverdlovsk Dermatological and Venereological Research Institute (deputy director: Professor N. P. Toropova, chief pediatric dermatologist of the Russian Federation Ministry of Health)

**32. Childhood cardiology**—Moscow NII of Pediatrics and Child Surgery, Russian Federation Ministry of Health (director: Professor Yu. Ye. Veltishchev)

**33. Childhood microsurgery**—Department of Child Surgery, Russian State Medical University (department head: Professor Yu. F. Isakov)

**34. Childhood traumatology and orthopedics**—St. Petersburg Pediatric Orthopedic Institute imeni G. I. Turner (director: Professor V. L. Andrianov)

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